NEWS UPDATES: National Academy will review EPA risk -assessment program (Greenwire)A

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

05/16/2012 03:16 PM

National Academy will review EPA risk-assessment program

Jeremy P. Jacobs, E&E reporter

Published: Wednesday, May 16, 2012

U.S. EPA announced today that the National Academy of Sciences will review the agency's efforts to upgrade its program for assessing the health risks posed by chemicals.

NAS will review steps taken by EPA's Integrated Risk Information System (IRIS) program to implement recommendations from a April 2010 NAS panel review of IRIS's formaldehyde assessment.

That panel criticized aspects of IRIS's methodologies and wrote an entire chapter on ways EPA should improve the program (***Greenwire*** , April 8, 2011).

From when the NAS review was released, EPA has welcomed the recommendations and vowed to implement them in a phased-in approach.

"EPA is committed to a strong and robust IRIS program," Lek Kadeli, EPA's acting assistant administrator for the Office of Research and Development, said in a statement. "This program plays a significant role in protecting the health of our country's citizens and the environment in which they live."

Specifically, EPA said NAS will review its efforts to improve current weight of evidence analyses -- which contribute to how the program selects which data should be considered in assessments -- as well as its approaches for weighing scientific evidence for chemical hazard identification.

Health assessments from the IRIS program often provide the foundational building blocks for EPA's and other agencies' public health recommendations. The program is currently conducting reviews of 550 chemicals that could post health risks, including controversial water contaminants such as hexavalent chromium.

The program has been repeatedly criticized, however, by industry and some government watchdogs for its methods and often laggard pace of completing assessments.

Republicans on Capitol Hill have also pressed the agency about IRIS, and last year's $1 trillion omnibus spending package included language requiring EPA to implement the NAS recommendations from its formaldehyde review. It also stipulated that EPA submit a progress report to Congress and send NAS "up to three" IRIS assessments for review (***Greenwire*** , Dec. 16, 2011).

EPA handed in the progress report to Congress at the end of last month, chronicling the first two phases of implementation. Those changes include a new document structure for IRIS assessments that is more streamlined and accessible. IRIS also plans to release two draft assessments in the near future that illustrate the changes.

The progress report, however, was met with sharp criticism from industry and Republicans who said it didn't address weight of evidence concerns. Democrats, however, defended IRIS, arguing that industry will criticize IRIS no matter what changes EPA makes (***E&E Daily*** , May 8).

The American Chemistry Council said today's announcement shows "more work is needed" for IRIS but welcomed the NAS review.

"We support the charge that has been given to the National Academies because it will allow [NAS] to examine the program's fundamental problems and evaluate the EPA's progress on implementing the recommendations that [NAS] provided to the agency last year," the trade group said in a statement.

"Specifically, we are encouraged the review will recommend approaches for weighing scientific evidence for both cancer and non-cancer, which is crucial to strengthening the scientific foundation of the program."

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NEWS UPDATES: Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

05/22/2012 09:44 AM

History: This message has been forwarded.

Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review

Posted: May 21, 2012

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"It's not like they have to wait and develop new guidance," the source adds. "There are plenty of examples out there on how to do weight of evidence appropriately."

The industry calls for EPA to develop guidance comes as the agency May 16 announced that the NAS will review the program, with recommendations expected in two years.

Academy officials proposed to conduct the review in lieu of reviewing two chemical assessments that Congress had originally sought. The NAS panel will "be charged to assess the scientific, technical, and process changes being implemented by EPA for IRIS," an NAS spokesman says (*Risk Policy Report*, May 1).

However, the NAS panel still plans to review the agency's pending assessment for inorganic arsenic, as lawmakers had called for in the agency's fiscal year 2012 spending bill, though EPA appears to have pulled its draft cancer assessment of the substance, according to its IRISTrack website.

In a statement announcing the NAS review, EPA said the academy "will also review current methods for weight of evidence analysis and recommend approaches for weighing scientific evidence for chemical hazard identification," among many other issues.

Top EPA officials have long indicated that they are considering plans for how to weigh scientific evidence when assessing chemicals but fear that use of such a framework could lead to further delays in a program often maligned for taking too long in producing IRIS assessments (*Risk Policy Report*, Nov. 1).

While industry has long called for weight-of-evidence analyses as part of IRIS assessments, EPA has failed thus far to institute any such practice into the process. In a report to Congress in April on the progress of IRIS reforms, the agency said it will craft weight-of-evidence guidelines in phase 3 of changes to the program, and will "approach or develop a new approach to consistently evaluate weight-of-evidence in IRIS assessments. EPA also will further work to develop systematic approaches to quantify uncertainty and variation." The agency is currently in phase 2 of the process, according to the report.

However, the industry source says without a data quality analysis, EPA cannot ensure the highest quality studies are being used as the basis for risk assessments, and waiting until the NAS finishes its review could mean as many as 50 assessments are released by the time the agency fixes the problem.

"There are ways to move forward with [guidelines] rather quickly, including methodologies" that have already been developed and tested by other groups, the source says. Such methods could be used in weighing data for assessments "without too much effort for EPA to move forward and put them in place pretty quickly . . . I don't think there is a lot of research and development necessary to implement these improvements."

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Fw: NEWS UPDATES: Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review (Risk Policy Report)

Kate Guyton to: Daniel Axelrad, Lauren Zeise, woodrufft 05/22/2012 12:21 PM

FYI....

----- Forwarded by Kate Guyton/DC/USEPA/US on 05/22/2012 12:20 PM -----

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Re: Fw: NEWS UPDATES: Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review (Risk Policy Report)

Daniel Axelrad to: Kate Guyton 05/22/2012 12:30 PM

History: This message has been replied to.

Hi Kate-

thanks for the article. Is NCEA still planning on doing a WOE workshop, or is that overtaken by the charge to the NAS committee? or undecided?

Kate Guyton FYI.... ----- Forwarded by Kate Guyton/DC/USEP... 05/22/2012 12:21:06 PM

From: Kate Guyton/DC/USEPA/US
To: Daniel Axelrad/DC/USEPA/US@EPA, Lauren Zeise <Lauren.Zeise@oehha.ca.gov>, woodrufft@obgyn.ucsf.edu
Date: 05/22/2012 12:21 PM
Subject: Fw: NEWS UPDATES: Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review (Risk Policy Report)

FYI....

----- Forwarded by Kate Guyton/DC/USEPA/US on 05/22/2012 12:20 PM -----

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NEWS UPDATES: Lack of transparency hinders U .S. risk-assessment effort -- former EPA toxics chief (Greenwire)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

04/19/2012 02:29 PM

Lack of transparency hinders U.S. risk-assessment effort -- former EPA toxics chief

Jeremy P. Jacobs, E&E reporter

Published: Thursday, April 19, 2012

U.S. EPA's system for assessing the health effects posed by chemicals lacks transparency and needs to more fully engage stakeholders, according to the former head of the agency's toxic substances office.

Speaking last night at a panel discussion hosted by George Washington University, Charles Elkins said EPA's Integrated Risk Information System (IRIS) needs to implement the policies outlined in the 1983 EPA "fishbowl" memo, meaning acting in such a way that the public can see its processes and it can see and interact with the public.

Elkins, who directed EPA's Office of Toxic Substances from 1986 to 1990 and is now a consultant with industry clients, also said IRIS needs to do a better job of engaging the scientific community throughout the system's assessment process.

"Assessments of the hazard of chemicals with complex sets of data inevitably result in conflicting interpretations of data," Elkins said. "Openly engaging in discussions of these conflicting interpretations can greatly enhance EPA's ability to make the right judgments and defend them against any criticism."

Elkins' remarks come as industry continues to criticize EPA's IRIS program, which sets standards that serve as the basis of regulations. IRIS has repeatedly been criticized by government watchdogs and the National Academy of Sciences (NAS).

An NAS review of IRIS's formaldehyde assessment last year called for significant improvements in the program's scientific methodologies (***Greenwire*** , April 8, 2011).

EPA, however, has welcomed the NAS recommendations and has taken several steps to implement them. Rebecca Clark, the acting director of EPA's National Center for Environmental Assessment said last night that Elkins' criticisms were off base.

"Every single assessment is in that fishbowl and is available for public comment," Clark said. "We embrace all the recommendations we got. ... [T]here is nothing that we disagree with [in the NAS report]."

Clark also said that the agency is establishing ways to seek public comment and peer review earlier in the IRIS process.

Elkins, however, charged that EPA has "gotten a little sloppy" with peer review and asked "where is EPA oversight" of the program.

He suggested a few ways to improve IRIS. First, he said EPA must engage the scientific community more fully on issues. He also called for an increased budget for the program and setting a more distinct timetable for the assessments so more are finished in a timely fashion and avoid lengthy reworking of assessments.

"These reforms are easy to implement," Elkins said. "The best regulatory programs within EPA have embraced them for years."

Clark noted that EPA is working to "streamline" the IRIS process. However, she noted that due to their complexity, "I am not sure we will ever get faster."

Lynn Goldman, dean of George Washington's School of Public Health and an expert on IRIS, suggested that there are deeper issues holding the program back -- including money.

She noted that it is unclear who should pay for IRIS assessments. With pharmaceuticals, she noted, industry pays for a Food and Drug Administration assessment because it is required before the drug can go on the market.

With chemicals, it is the exact opposite: Industry can put a chemical into commerce without a health review. So, she concluded, there is no fundamental incentive for industry to cooperate with EPA's process.

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NEWS UPDATES: Seeing Slow Pace, EPA Crafts Plan To Speed Issuance Of Risk Assessments (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

07/03/2012 09:51 AM

Seeing Slow Pace, EPA Crafts Plan To Speed Issuance Of Risk Assessments

Posted: July 2, 2012

EPA is acknowledging that its human health risk assessment program is not "fully" meeting the agency's needs, but the program has crafted a new five-year strategic plan that seeks to speed completion of the documents that are often the basis of agency decisions and regulations.

EPA's human health risk assessment program is part of the agency's research office, and includes its influential Integrated Risk Information System (IRIS) database of toxicological assessments as well as the Integrated Science Assessments (ISAs) of criteria air pollutants defined in the Clean Air Act, Provisional Peer Reviewed Toxicity Values (PPRTVs) for cleanup sites and methodologies to undergird these and similar products. The IRIS assessments and ISAs, in particular, are often the basis for agency decisions and rules.

But the program acknowledges in its June 2012 plan governing fiscal years 2012-2017 that while agency decisions must be based on "scientifically-defensible evaluations of data" that are relevant to assessing human health impacts, "the current demand for human health assessments of individual chemicals and chemical mixtures is not being fully met." *The plan is available on InsideEPA.com. See page for 2 details.* (*Doc ID:* 2403407)

The problem is not new -- as long ago as 2008, agency science advisors urged EPA to increase the output of IRIS assessments, arguing that the documents are very valuable to assessors and risk managers worldwide, but many are out of date. The agency has struggled to deal with this issue, as well as efforts to streamline the process by which it re-evaluates existing chemicals and prepares new assessments. Still, most assessments take more than the targeted two-year time line.

The latest five-year plan includes a vision of generating "timely, credible human health assessments of individual chemicals and chemical mixtures to support priority EPA risk management decisions, thereby enabling EPA to better predict and prevent risk," but does not appear to address how the agency will attempt to solve the problem it has identified.

The document also describes many of the efforts EPA has implemented in order to bolster the IRIS program following a harsh critique from the National Academy of Sciences (NAS) in 2011 of the agency's draft formaldehyde assessment. Many of the improvements are intended to make the documents easier to read, by rigorous editing, the addition of a preamble and summary that explain the document and how its conclusions were reached as well as new graphics.

Some of the recently released draft assessments, such as the draft assessment of trimethylbenzene, have adopted these changes *(see related story)* .

EPA has also promised substantive changes, and some of these are enumerated in the document, including updates to the web-based IRIS database, its IRIS Track website for checking the status of ongoing assessments and its newer database for all studies referenced in IRIS assessments. "These improvements will increase database utility for both chemical managers and users of the database. Users looking for existing literature and assessments of related chemicals, adverse outcomes or modes of action will experience improved ease of access," according to the plan.

"Additionally, literature reviews of assessments under development, which are currently made publicly available and announced in the *Federal Register* , will also be made available in the Health and Environmental Research Online (HERO) database."

The "summary table of outputs and outcomes" lists just nine IRIS assessments for completion in fiscal year 2012. Of these, three -- for dichloromethane, tetrachloroethylene and dioxin (non-cancer) -- have already been published. The remainder -- halogenated platinum salts, ethylene oxide, n-butanol, 1,4-dioxane and methanol

(non-cancer) -- remain works in progress. The table lists 15 assessments that will be released in fiscal year 2013, among them assessments of benzo-a-pyrene, Libby asbestos, PCBs, uranium and a PAH mixture.

The output tables also list a number of activities intended to support IRIS, though none has a schedule. Among these projects are efforts such as "Communicate with stakeholders on approaches to recurring statistical and dose-response issues in IRIS Assessments," mode of action (MOA) "scientific support for IRIS Chemical Managers" and "Communicate with stakeholders on approaches to recurring MOA issues in IRIS Assessments (e.g. memorandum and white papers)."

These issues are among the more contentious issues in IRIS assessments, particularly EPA's conclusions on MOA, because these decisions determine how strictly a carcinogen's risk is calculated.

By contrast, the ISA program assesses only the six criteria pollutants defined in the Clean Air Act, including lead, particulate matter, ozone, nitrous oxides and sulfur dioxide, on a five-year cycle. NAS pointed to the recently revamped ISA process as a potential model for IRIS in its 2011 formaldehyde report.

The report's table also outlines a number of new products underway that are intended to support the program's assessments. Most are due in fiscal year 2014, or later years. Among the projects are "A publication in the peer-reviewed scientific literature that describes methods and models for evaluating associations between health outcomes and chemical and non-chemical stressors (and assessing interactions between stressors): analyses of socio-economic status and other vulnerability factors" with output year 2015 as well as an "Internal Technical Report to support the Risk Assessment Forum's Cumulative Risk Assessment guidelines development," with output year 2014 and a "Toolbox for health assessors to generate mode of action pathway maps that demonstrate the size and strength of associations graphically using the MOA knowledgebase to graphically display what is known about toxicity/disease pathways and modes of action to inform weight of evidence analysis for hazard characterization of assessments." -- *Maria Hegstad*

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NEWS UPDATES: EPA to review health effects of 15 substances (Greenwire)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew 05/07/2012 10:07 AM

EPA to review health effects of 15 substances

Jeremy P. Jacobs, E&E reporter
Published: Friday, May 4, 2012

U.S. EPA plans to begin reviewing the health effects of 15 chemicals this year, a step that could lead to new regulations on environmental contaminants.

The list, due to be published Monday in the *Federal Register* , includes high-profile substances believed to have toxic effects on humans, including mercury, methylmercury and chlorobenzene, a solvent used in making pesticides and as a degreaser for auto parts.

EPA selected the chemicals for Integrated Risk Information System (IRIS) assessment by reviewing nominations from EPA, other agencies and the public. Some on the list have also been on IRIS's agenda previously but were delayed due to resource limitations.

Chlorobenzene, methylmercury, mercury and vanadium are priorities for multiple EPA offices, the agency said, and "all chemicals have the potential for high impact on public health."

Mercury has long been considered hazardous, and EPA and states have taken steps to limit its use in everything from car parts to home thermostats.

Methylmercury is ingested by fish after mercury in air pollution has rained into rivers and lakes. It is believed to bioaccumulate in fish and other animals, leading to human exposure when it is eaten.

Chlorobenzene does not occur naturally but has been used in the manufacture of many pesticides, including the now-banned DDT. It is also used as a degreaser and can persist in soil for many days. EPA has said humans are primarily exposed to the substances in occupational settings, and exposure can lead to nervous system effects. It is unclear whether it causes cancer.

Vanadium is also a soil contaminant and is primarily found in steel and aluminum alloys used in auto parts.

Another notable substance on the list is antimony, which is used in batteries and in flame retardants such as those used on children's toys and clothing.

IRIS health assessments are often the building blocks for new regulations, including drinking water standards, cleanup goals and ambient air limits. The program has been repeatedly criticized by government watchdogs, including the Government Accountability Office, for its laggard pace as well as by industry and congressional Republicans for what they view as inadequate scientific methodologies.

In the past year, EPA has vowed to improve the program, including implementing the

recommendations of a National Academy of Sciences review of last year's IRIS formaldehyde assessment. Those updates include a more streamlined process and more opportunity for public comment and peer review.

The American Chemistry Council (ACC) said the announcement reinforces their criticisms.

"This action underscores our overall concerns with the IRIS process and EPA's ability to manage a transparent and objective science-based process," the trade group said in a statement. "It's not entirely clear how EPA responded to nominations for new chemical assessments or why certain chemicals were prioritized over others for review."

ACC also expressed concern over whether the 52 ongoing IRIS assessments will benefit from the NAS recommendations. "It's critical that EPA take the necessary steps to ensure those assessments deliver credible results in a timely manner," ACC said.

The list outlined other IRIS actions, as well.

Notably, EPA is deferring on whether it will conduct an IRIS assessment for lead -- a potent neurotoxin -- until the end of 2012. The agency said it will wait for a final Integrated Science Assessment this summer, which should provide a "comprehensive summary of health and ecological scientific evidence" on the substance.

EPA also said it is withdrawing its IRIS assessment of the controversial plastic additive bisphenol A (BPA). The agency said it is awaiting further results from the Food and Drug Administration and National Institutes of Health "prior to determining whether agency action under the [1976] Toxic Substances Control Act is required for protection of public health."

Public health advocates have frequently criticized EPA for its lack of action on BPA. The agency has sought to add BPA to its "chemicals of concern" list, which could lead to new regulations, but that proposal has been stuck at the White House Office of Management and Budget for nearly two years (***E&E Daily*** , Sept. 13, 2011).

Additionally, the agency said that it is combining cancer and noncancer assessments for arsenic into one review. It is also merging oral and inhalation assessments of hexavalent chromium, the industrial solvent well-known as the contaminant from the 2000 film "Erin Brockovich."

Click here for the full list.

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EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies

Posted: March 19, 2012

EPA efforts to reform its controversial Integrated Risk Information System (IRIS) program is winning cautious praise from some federal agencies that have strongly criticized the program, which could bolster EPA efforts to defend the program as it prepares to submit an upcoming report on the issue to lawmakers.

"EPA is doing an impressive amount of work" on IRIS and the program "is looking better," as a result, says a source with one federal agency that has levied criticism in the past. "I'm surprised EPA is able to do as much as they're doing with the resources they have," the source adds.

And Kevin Bromberg, of Small Business Administration's (SBA) Office of Advocacy, told attendees at the chemical industry conference GlobalChem in Baltimore March 6 that that it "looks like we're seeing substantial progress and improvements" in the IRIS program. "We're cautiously optimistic," Bromberg said, citing EPA's recent assessments of perchloroethylene (perc) and tetrahydrofuran (THF) as examples of the positive improvements.

In a March 14 letter to Lek Kadeli, the acting head of EPA's Office of Research and Development (ORD), SBA also praised the agency's recent decision to delay its assessment on hexavalent chromium (Cr6) so it can weigh new industry studies that cast doubt on the agency's draft assessment.

"EPA's actions will enhance the scientific integrity of this review and will help to increase confidence in the IRIS program more generally," the letter says. SBA "is pleased that EPA is taking seriously its commitment to rigorous independent expert peer review as well as its commitment to using the best available science." *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2393515)

Several federal agencies -- especially those like the Department of Defense and NASA that could face greater cleanup liability as a result of new risk assessments -- have strongly criticized EPA's IRIS assessments for being overly conservative and lacking scientific basis. In 2010, several federal agencies raised concerns that the Obama administration's revised process for crafting the assessments limited their roles and review times (*Risk Policy Report* , May 11, 2010).

Since then, pressure has grown on EPA to revise its IRIS assessment process after the National

Academy of Sciences (NAS) strongly criticized the agency's draft formaldehyde assessment and recommended the agency make a host of additional reforms.

EPA has adopted some additional steps to reform the program -- including creation of a standing scientific panel to review its draft assessments -- and is also crafting others to comply with NAS recommendations, such as an upcoming weight of evidence framework to use in drafting the assessments.

But Congress, in EPA's fiscal year 2012 budget, also required EPA to submit as many as three additional draft assessments, including its arsenic assessment, to NAS for review, rather than review by agency Science Advisory Board or a contractor-created expert panels -- options EPA generally prefers.

Lawmakers also required EPA to detail how each of the assessments it releases in FY12 meets the NAS recommendations, and requests a report from EPA on how it is progressing with the NAS reforms by March 1.

While EPA has not yet submitted the report to Congress, a draft version is under review by other agencies. "As requested in the report language for the Consolidated Appropriations Act of 2012, EPA has prepared an IRIS progress report to Congress," an EPA spokeswoman says. "This report is currently undergoing review and will be sent to Congress as soon as it completes that review."

But with SBA's Bromberg and others praising the reforms EPA has made so far, the interagency review could result in a favorable report to Congress.

The agency source says EPA's upcoming report to Congress is optimistic and praised the changes EPA is already implementing. The source especially welcomed EPA efforts to make its assessments more accessible. "I give them a lot of credit for the [new evidence] tables, making [new IRIS documents] concise," the source says. The source adds that another reform expected to begin this summer, of providing an early discussion session with stakeholders on key scientific issues before beginning to draft assessments "could be critical. EPA will be very much informed."

In his remarks to GlobalChem, Bromber was especially pleased with EPA's recent perc and THF assessments. He noted that with the perc assessment, "EPA changed the endpoint evaluation consistent with peer reviewer recommendations." With THF, Bromberg praised EPA's decision not to calculate a cancer risk estimate because of the uncertainty of its evidence -- a conclusion that Bromberg said EPA should have made with arsenic.

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NEWS UPDATES: National Academies Set to Review IRIS Assessment Development Procedures (BNA)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

05/21/2012 02:37 PM

National Academies Set to Review IRIS Assessment Development Procedures

Monday, May 21, 2012

from Chemical Regulation Reporter ®

NAS Review of IRIS Assessment Process

Key Development: A branch of the National Academies will begin a comprehensive review of EPA's Integrated Risk Information System assessment development process.

Potential Impact: The review board will offer recommendations that could alter how IRIS assessments are developed.

By Anthony Adragna

The National Academies will undertake a comprehensive review of the Environmental Protection Agency's Integrated Risk Information System assessment development process, EPA announced May 16.

The National Research Council, a branch of the National Academies, will assess the current process for developing IRIS assessments and analyze improvements suggested by the academies in April 2011 that have been partially implemented by EPA.

The IRIS system provides health information on 550 chemicals that may be present in the environment. EPA uses the assessments to inform rulemakings and says the assessments support the agency's mission of protecting human health and the environment.

A National Academies panel leveled a number of criticisms at the chemical assessment process while examining a draft formaldehyde review in April 2011. The panel said the agency's IRIS reports are often too long and redundant, they do not present scientific information clearly, and they fail to explain the agency's rationale for determining whether or not not a chemical causes health problems (35 CRR 379, 4/11/11).

IRIS reports on ammonia and two trimethylbenzenes will be submitted for peer review this summer using a new document structure developed by EPA in response to the April 2011 recommendations, the agency said in a report provided to Congress in April. EPA was required to submit the report to the House and Senate Appropriations committees under the Consolidated Appropriations Act of 2012 (Pub. L. No. 112-74)(36 CRR 496, 5/7/12).

The National Research Council review will consider current methods of conducting weight-of-evidence analyses and will recommend new approaches for chemical hazard identification.

Industry Pleased.

The American Chemistry Council, which represents leading chemical manufacturers, said it supported the NRC review and was pleased the academy would recommend new approaches for weighing scientific evidence.

“Until such improvements are made, the program will continue to produce assessments that create unnecessary confusion and fail to properly guide public health decisions,” the council said in a May 16 statement to BNA. “We have deep concerns that the entire generation of draft, and final IRIS assessments, that have been or will be issued this year, will suffer from many of the very same critical scientific shortcomings that plagued the draft formaldehyde assessment.”

Jack Synder, executive director of the Styrene Information & Research Center, which represents styrene manufacturers, said the center was pleased with EPA's progress in implementing the recommendations from the formaldehyde report, but he said the new review would ensure the integrity of IRIS reports.

“We believe this more comprehensive NAS examination of the IRIS process will help further strengthen the quality of future IRIS assessments,” he said in a statement to BNA. The report will help to “ensure EPA's pending IRIS review of styrene will be as thorough and scientifically balanced as possible.”

Environmental Group Disappointed.

Daniel Rosenberg, senior attorney for the Natural Resources Defense Council, said the EPA announcement was not unexpected, but the review was not a “particularly good use of the NAS time.”

Rosenberg said the chemical industry had launched a massive campaign to undermine the credibility of independent scientists. He said it would be troubling if there were chemical industry representation on the review panel.

The Environmental Defense Fund was unavailable for comment.

By Anthony Adragna

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Fw: NEWS UPDATES: EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies (Inside EPA)

Kate Guyton to: iir 03/20/2012 10:12 AM

Perky news! :-)

EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies

Posted: March 19, 2012

EPA efforts to reform its controversial Integrated Risk Information System (IRIS) program is winning cautious praise from some federal agencies that have strongly criticized the program, which could bolster EPA efforts to defend the program as it prepares to submit an upcoming report on the issue to lawmakers.

"EPA is doing an impressive amount of work" on IRIS and the program "is looking better," as a result, says a source with one federal agency that has levied criticism in the past. "I'm surprised EPA is able to do as much as they're doing with the resources they have," the source adds.

And Kevin Bromberg, of Small Business Administration's (SBA) Office of Advocacy, told attendees at the chemical industry conference GlobalChem in Baltimore March 6 that that it "looks like we're seeing substantial progress and improvements" in the IRIS program. "We're cautiously optimistic," Bromberg said, citing EPA's recent assessments of perchloroethylene (perc) and tetrahydrofuran (THF) as examples of the positive improvements.

In a March 14 letter to Lek Kadeli, the acting head of EPA's Office of Research and Development (ORD), SBA also praised the agency's recent decision to delay its assessment on hexavalent chromium (Cr6) so it can weigh new industry studies that cast doubt on the agency's draft assessment.

"EPA's actions will enhance the scientific integrity of this review and will help to increase confidence in the IRIS program more generally," the letter says. SBA "is pleased that EPA is taking seriously its commitment to rigorous independent expert peer review as well as its commitment to using the best available science." *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2393515)

Several federal agencies -- especially those like the Department of Defense and NASA that could face greater cleanup liability as a result of new risk assessments -- have strongly criticized EPA's IRIS assessments for being overly conservative and lacking scientific basis. In 2010, several federal agencies raised concerns that the Obama administration's revised process for crafting the assessments limited their roles and review times (*Risk Policy Report* , May 11, 2010).

Since then, pressure has grown on EPA to revise its IRIS assessment process after the National

Academy of Sciences (NAS) strongly criticized the agency's draft formaldehyde assessment and recommended the agency make a host of additional reforms.

EPA has adopted some additional steps to reform the program -- including creation of a standing scientific panel to review its draft assessments -- and is also crafting others to comply with NAS recommendations, such as an upcoming weight of evidence framework to use in drafting the assessments.

But Congress, in EPA's fiscal year 2012 budget, also required EPA to submit as many as three additional draft assessments, including its arsenic assessment, to NAS for review, rather than review by agency Science Advisory Board or a contractor-created expert panels -- options EPA generally prefers.

Lawmakers also required EPA to detail how each of the assessments it releases in FY12 meets the NAS recommendations, and requests a report from EPA on how it is progressing with the NAS reforms by March 1.

While EPA has not yet submitted the report to Congress, a draft version is under review by other agencies. "As requested in the report language for the Consolidated Appropriations Act of 2012, EPA has prepared an IRIS progress report to Congress," an EPA spokeswoman says. "This report is currently undergoing review and will be sent to Congress as soon as it completes that review."

But with SBA's Bromberg and others praising the reforms EPA has made so far, the interagency review could result in a favorable report to Congress.

The agency source says EPA's upcoming report to Congress is optimistic and praised the changes EPA is already implementing. The source especially welcomed EPA efforts to make its assessments more accessible. "I give them a lot of credit for the [new evidence] tables, making [new IRIS documents] concise," the source says. The source adds that another reform expected to begin this summer, of providing an early discussion session with stakeholders on key scientific issues before beginning to draft assessments "could be critical. EPA will be very much informed."

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Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

03/01/2012 10:47 AM

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Faulting Industry, Activists Push EPA To Adopt Strict NAS-Backed IRIS Fixes

Posted: February 29, 2012

Environmentalists are calling on EPA and other federal agencies to implement a broader range of National Academy of Sciences (NAS) advice for improving their chemical risk assessment programs than industry is seeking, a move that puts pressure on the agencies to adopt stricter assessment methods than they currently use, including assessments of cumulative and low-level exposures and conservative modeling in the face of scientific uncertainties.

"[Industry] cherry-picking their favorites amongst the NAS recommendations does not constitute 'sound science,'" Jennifer Sass of the Natural Resources Defense Council (NRDC) wrote in a Feb. 22 blog post. "The EPA . . . and other federal agencies should begin implementing these important [NAS] recommendations, and our political leaders should be supporting those efforts, not simply ordering the science they prefer off the menu provided by the chemical industry."

NRDC and the Scientific Health Experts Network Feb. 22 also unveiled a new issue paper, "Strengthening Toxic Chemical Risk Assessments to Protect Human Health," that urges EPA and other agencies to weigh the recommendations in a host of recent NAS papers addressing risk assessment programs -- not just the advice contained in NAS' review of EPA's integrated risk information system (IRIS) assessment of formaldehyde that industry groups have been urging policymakers to adopt.

Specifically, the paper says EPA and other agencies should follow the recommendations in three NAS papers: "Toxicity Testing in the Twenty-first Century: A Vision and a Strategy" from 2007, "Phthalates and Cumulative Risk Assessment: The Tasks Ahead" released the following year and "Science and Decisions: Advancing Risk Assessment" published in 2009.

The groups' issue paper says that if EPA were to move forward with implementing those provisions, it "would significantly improve current practices."

A source familiar with the paper says that its release is an effort to "prod EPA to develop priorities for implementing ["Science and Decisions"], a timeline with short and long-term goals, and some public accountability and transparency in the process." While the agency has been undergoing internal conversations to move forward on the issue, it has been "in a sort of haphazard way, with no clear written plan that the public can review or comment on, no clear timelines, and therefore no transparency or accountability," the source says.

The paper has been released as industry and congressional Republicans have been pushing the agency to adopt recommendations contained in chapter 7 of the NAS' highly critical review of EPA's formaldehyde assessment.

The formaldehyde report, released last April, found that EPA did not provide sufficient evidence to support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma. And its chapter 7 -- which includes many initiatives from earlier NAS reports, in particular "Science and Decisions -- made recommendations for changes to EPA's overall IRIS process and scientific approach for drafting assessments and raised concerns about EPA's process for reaching weight of evidence conclusions in its risk assessments.

Demanding IRIS Changes

Industry and congressional Republicans have rallied around chapter 7 since its release, using it to both demand changes to IRIS and question agency science. Agency critics have also called on EPA to stall all assessments until the NAS-recommended changes in chapter 7 were made -- a request EPA did not move forward with.

But congressional Republicans have also required EPA to subject its upcoming arsenic assessments and up to two others to NAS for review to ensure that the agency is following the chapter 7 recommendations. The agency has said the first of these consultations is under consideration for the summer of 2012, and would likely entail a toxicological issue regarding mouse lung tumors relevant to three ongoing IRIS assessments of ethylbenzene, napthalene and styrene.

And EPA has already announced numerous changes intended to address the NAS formaldehyde report. Many seek to make IRIS documents more transparent and easier to read but the agency has also announced the creation of a permanent standing committee to review IRIS assessments and is adopting a standardized weight of evidence framework to use in drafting the assessments.

Sass said in her blog post that despite industry's "recent spate of [NAS] fever," the efforts from chemicals groups and Republicans have been misguided. While those groups are pressuring EPA to implement every provision in chapter 7, they have "been silent or hostile to" the other recent NAS reports that contain "far-reaching, and health-protective recommendations," Sass wrote.

While industry has pushed EPA to implement advice in the formaldehyde review, their response to the other NAS reports on risk assessment has been less enthusiastic.

Cal Dooley, president and CEO of the American Chemistry Council, said in an interview last August that chapter 7 of the formaldehyde report "provided a road map for EPA to reform and improve their IRIS assessments, and we look at it as one of the more recent critiques that provides a sound proposal so they can ensure that the best science based process that results in the most credible scientific conclusions on assessing the various materials."

When asked about why the group was not focusing on "Science and Decisions" and other NAS

reports issued before the formaldehyde report, Dooley said "we are generally are pretty supportive of NAS and the reports that they have issued," though he declined to expand.

In the issue paper, NRDC and the health experts network calls for four main areas of reform: the need to "identify and incorporate variability in human exposure and vulnerability into health assessments" to better protect vulnerable populations; incorporate "science based default assumptions that protect health, rather than waiting for more data" for instances where data is missing or unreliable to speed up the assessment process; efforts to take into account "information about the potential impacts of exposure to multiple chemicals" and other factors, "such as exposure to biological and radiological agents, and social conditions"; and the need to assume that since humans are exposed to multiple chemicals "it cannot be presumed that any--even low level-- exposures are risk-free. It should be assumed that low levels of exposures are associated with some level of risk, unless there are sufficient data to contradict this assumption."

Narrow Variability View

Despite the NAS giving considerable weight to these issues in its reports, EPA has failed to institute them, the paper argues, taking instead a narrow view of variability, preferring to wait on long running scientific studies or assuming a lack of data means there is no adverse effect, failing to use conservative defaults in the place of missing data and other information, exposures to multiple chemical and non-chemical stressors and low-level exposures.

"Currently, the policies that determine how industrial chemicals are regulated presume that the chemicals are safe in the absence of an assessment," according to the paper. "This can be reversed by setting default, interim health-protective standards and restrictions pending completion of a risk assessment. Such a default would stimulate more research, reward chemical manufacturers for producing data instead of avoiding it, and remove many of the incentives that chemical manufacturers now use to delay final assessments. This could be done right away, while agencies plan how to implement the NAS' recommendations."

In the meantime, the paper continues, "these reports have been languishing without the focus and attention they deserve." -- *Jenny Hopkinson* (jhopkinson@iwpnews.com This e-mail address is being protected from spambots. You need JavaScript enabled to view it)
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NEWS UPDATES: EPA Seeks 'Engagement' Rules To Help Speed IRIS Chemical Risk Reviews (Inside EPA)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

11/20/2012 12:02 PM

EPA Seeks 'Engagement' Rules To Help Speed IRIS Chemical Risk Reviews

Posted: November 19, 2012

EPA officials say they are seeking to craft "rules of engagement" that will allow competing interest groups to discuss relevant scientific issues before the agency drafts chemical risk assessments for its Integrated Risk Information System (IRIS) program while still allowing the agency to meet speedy 23-month deadlines for completing assessments.

"I know the playing field [between industry and environmentalists] isn't level. I appreciate that opening the door [to extensive consultations] could exacerbate the problem," Vincent Cogliano, the IRIS program's acting director, told a Nov. 13 stakeholder meeting in Arlington, VA.

"But I don't want to go backward. Can we think about rules of engagement -- can we keep the doors [of discussion] open?" he said.

Cogliano was responding to competing calls from industry and some state officials seeking extensive consultation and assurances over the science the agency uses in its pending risk assessments and environmentalists and other states concerned that such extensive interactions could delay the assessments even more than they already are.

"Environmentalists don't trust industry, industry doesn't trust environmentalists, nobody trusts EPA and the states and academics think we're all crazy," former EPA official Chuck Elkins, now an industry consultant, told the meeting. He urged EPA to conduct the program more transparently, set firmer deadlines for assessment milestones and explain why deadlines are not being met. "EPA ought to conduct the program in a fishbowl," he said, adding that the agency needs to adopt "verification programs" to better track progress.

And he welcomed plans by Kenneth Olden, the new director the National Center on Environmental Assessment (NCEA), which oversees IRIS, for seeking early input. Elkins said one of the reasons for lack of trust was EPA's pattern of "anti-engagement" on IRIS assessments, adding that he hoped "plenty of engagement at arms' length will help everyone."

Cogliano, the IRIS director, agreed, asking "How do we build trust that all judgments are handled well [in the program]? It's not going to happen overnight. That's one of the reasons we really want to push early engagement. Not something that will just be developed by EPA."

Some industry officials also suggested the agency again consider a pilot program in which industry conducts draft versions of risk assessments. But environmentalists rejected the suggestion, noting that the Bush administration had canceled an earlier effort first launched in the Clinton administration.

EPA efforts to resolve the competing concerns are the latest hurdle for the program -- which is considered the gold standard for chemical risk assessments that are used to set a host of regulatory standards.

In 2008, the Government Accountability Office (GAO) listed the program as a "high risk" because it generally took so long -- sometimes a decade or more -- to complete assessments. In 2009, Administrator Lisa Jackson sought to revise the IRIS review process, setting a goal of 23 months to complete assessments.

But since setting the goal, the program has stumbled. A National Research Council (NRC) review of its draft formaldehyde assessment drew extensive criticism for not containing adequate justification for its finding that the chemical is a leukemogen. The NRC panel also urged EPA to revise its IRIS assessment process, calls that have become a rallying cry for industry groups.

While EPA has adopted some of the NRC panel's advice, it is still working to develop other reforms. In addition, a

pending NRC review of the program -- not expected to be completed until 2014 -- is likely to recommend additional changes.

Even as the NRC review begins, Olden, the new NCEA director, has promised an aggressive effort to address longtime concerns with the program. Using the scientific review process for the agency's ambient air quality standards could serve as a model, he said. He intends to solicit input on how assessments should be crafted, what data is available and should be used, what data gaps exist before the agency staff begin their first draft of the assessment.

Olden has also launched a public outreach campaign to discuss potential changes and gain input from federal agencies, industry, environmentalists, states and others, including the Nov. 13 public meeting.

Cogliano told the meeting that agency officials have set a high bar for the program and would like to be able to compete the assessments quickly. Asked about the program's progress on cumulative risk assessments, Cogliano replied, "The first step is you have to know the toxicity of all the different chemicals people are exposed to. We really want to have it all in the database."

At the same time, he said the agency hopes to improve the "throughput" of IRIS by getting beyond the "single digits" of assessments it has completed in the recent past. "That's not acceptable, it's not what the American people need and want," he added.

Olden agreed, saying he would like the agency to take three or four chemicals and complete the assessments in 23 months. "Let's decide whether it is or is not [doable]," he said.

Environmentalists and some state officials also called for the agency to speed its assessments, and warned that industry calls for greater consultation would lead to further delays. "I'm concerned that one set of [issues] dominate the other. IRIS has repeatedly allowed demands for more and more certain data to impede the completion of assessments," said Richard Denison, senior scientist with the Environmental Defense Fund. "All of the rewards of the delay fall toward one side, regulated industry, and all the risks fall to the public. Clear consequences must follow if deadlines are missed."

He said that despite Jackson's changes to the review process in 2009, not a single assessment has met the new, 23-month deadline. "The average completion time for these assessments is 7.4 years, nearly four times longer than the goal of 23 months," Denison said. "IRIS needs fewer, not more opportunities for public input. It's indisputable that leads to delay. It results in a process that virtually ensures the input EPA receives is imbalanced and badly skewed toward the regulated community . . . We simply must stop pretending that there is a level playing field . . . With more such opportunities, the greater the imbalance becomes."

Echoing longstanding calls from the Center for Progressive Reform, a think tank that favors stricter environmental regulation, Denison proposed reducing the number of opportunities for public comment to one period when the public and other federal agencies can respond simultaneously. Denison suggested one comment period at the beginning regarding EPA's plans for the draft, and a second comment period on the draft document.

Stephen Lester, science advisor for the Center for Environment, Health & Justice, questioned industry and other criticism about the IRIS program, arguing that "the work coming out of this program is good . . . and that is not broken. It can be improved," he said. "The people I'm working with at the grassroots level suffer because numbers and levels don't come out. There's real frustration around getting the best science. The reach of industry isn't a benefit. You cannot make them happy because it's not the details, it's about the process." Lester also questioned when the program will begin to address a concern of his, cumulative risk.

But David Fisher, general counsel at the American Chemistry Council (ACC), said his group is "trying to take advantage to make the peer review more substantive and helpful. If we are going to invest more resources into peer review . . . and making sure EPA's really given a hard look at the [peer review recommendations]. The notion is not to slow things up but to garner [more from the investment]."

Fisher said that IRIS documents represent the policy of not just EPA, but the political administration as well. As a result, they should be vetted by other agencies and changed as a result before the document is released publicly, he said.

Similarly, General Electric Co. counsel Pat Casano questioned how EPA will ever be able to increase the program's output. She suggested EPA consider piloting a program "where industry does the risk assessments," an approach that is already being implemented by the European Union's REACH program. "I don't think EPA is ever going to have the resources to review every chemical. There's no harm in piloting a few of these," Casano said.

But Denison and Jennifer Sass, a senior scientist with the Natural Resources Defense Council, rejected her suggestion. "You've probably put your finger on the part of REACH with the least support in the environmental-NGO community," Denison said. "I do not think that model would fly here."

Denison and Sass said that EPA and industry had tried a similar approach during the Clinton administration when industry was tasked with proposing first drafts of assessments for several chemicals, including ethylene oxide and vinyl chloride. But the Bush administration later ended the pilot because of concerns about the draft assessments' quality, Sass said.

But Casano argued that "we have to get past the trust issue. There's a bigger picture here." She pointed to calls for reform of the Toxic Substances Control Act, as well as reformers' refrain that industry should prove its chemicals are safe. "If you want that, you have to accept industry [data and scientists]. There is a trust issue, but I think that things EPA is doing with weight of evidence [tools] and peer review . . . would get us past that."

Representatives from state environmental departments also appeared split over how EPA should proceed. Gloria Post, a toxicologist with New Jersey's Department of Environmental Protection, said assessments should not be delayed indefinitely, and called for new studies to be better defined. "It should be kept in mind that risk assessment is a process used to make decisions in the absence of complete information," Post said.

Similarly, Gary Ginsberg, a senior toxicologist with Connecticut's Department of Public Health, echoed Post's concerns. "The public suffers, and it's the only stakeholder suffering by delay," he said.

Ginsberg noted that when EPA decides to suspend an IRIS assessment to await new studies, "It might be good for EPA to put out what the default approach would get you, what is the value of the new information, is it worth waiting for. Maybe we don't agree with EPA on waiting. That all needs to be transparent -- What the research is, what uncertainties is it attacking."

But Joseph Haney, a toxicologist with Texas Commission on Environmental Quality (TCEQ), provided a different perspective. The state has threatened to avoid using IRIS assessments in its decision-making and regulations, and work only from its own assessments following its concerns with what it considered overly stringent draft assessments of arsenic, formaldehyde and hexavalent chromium, and a similarly overly stringent assessment for dioxin.

"TCEQ has traditionally considered IRIS the gold standard. While Texas has concerns about [some of the assessments that have been released in recent years] TCEQ's confidence could be renewed if [the issues] could be addressed [and early input considered]." -- *Maria Hegstad*

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But congressional Republicans have also required EPA to subject its upcoming arsenic assessments and up to two others to NAS for review to ensure that the agency is following the chapter 7 recommendations. The agency has said the first of these consultations is under consideration for the summer of 2012, and would likely entail a toxicological issue regarding mouse lung tumors relevant to three ongoing IRIS assessments of ethylbenzene, napthalene and styrene.

And EPA has already announced numerous changes intended to address the NAS formaldehyde report. Many seek to make IRIS documents more transparent and easier to read but the agency has also announced the creation of a permanent standing committee to review IRIS assessments and is adopting a standardized weight of evidence framework to use in drafting the assessments.

Sass said in her blog post that despite industry's "recent spate of [NAS] fever," the efforts from chemicals groups and Republicans have been misguided. While those groups are pressuring EPA to implement every provision in chapter 7, they have "been silent or hostile to" the other recent NAS reports that contain "far-reaching, and health-protective recommendations," Sass wrote. While industry has pushed EPA to implement advice in the formaldehyde review, their response to the other NAS reports on risk assessment has been less enthusiastic.

Cal Dooley, president and CEO of the American Chemistry Council, said in an interview last August that chapter 7 of the formaldehyde report "provided a road map for EPA to reform and improve their IRIS assessments, and we look at it as one of the more recent critiques that provides a sound proposal so they can ensure that the best science based process that results in the most credible scientific conclusions on assessing the various materials."

When asked about why the group was not focusing on "Science and Decisions" and other NAS reports issued before the formaldehyde report, Dooley said "we are generally are pretty supportive of NAS and the reports that they have issued," though he declined to expand.

In the issue paper, NRDC and the health experts network calls for four main areas of reform: the need to "identify and incorporate variability in human exposure and vulnerability into health assessments" to better protect vulnerable populations; incorporate "science based default assumptions that protect health, rather than waiting for more data" for instances where data is missing or unreliable to speed up the assessment process; efforts to take into account "information about the potential impacts of exposure to multiple chemicals" and other factors, "such as exposure to biological and radiological agents, and social conditions"; and the need to assume that since humans are exposed to multiple chemicals "it cannot be presumed that any--even low level-- exposures are risk-free. It should be assumed that low levels of exposures are associated with some level of risk, unless there are sufficient data to contradict this assumption."

Narrow Variability View

Despite the NAS giving considerable weight to these issues in its reports, EPA has failed to institute them, the paper argues, taking instead a narrow view of variability, preferring to wait on long running scientific studies or assuming a lack of data means there is no adverse effect, failing to use conservative defaults in the place of missing data and other information,

exposures to multiple chemical and non-chemical stressors and low-level exposures.
"Currently, the policies that determine how industrial chemicals are regulated presume that the chemicals are safe in the absence of an assessment," according to the paper. "This can be reversed by setting default, interim health-protective standards and restrictions pending completion of a risk assessment. Such a default would stimulate more research, reward chemical manufacturers for producing data instead of avoiding it, and remove many of the incentives that chemical manufacturers now use to delay final assessments. This could be done right away, while agencies plan how to implement the NAS' recommendations."
In the meantime, the paper continues, "these reports have been languishing without the focus and attention they deserve." -- Jenny Hopkinson (jhopkinson@iwpnews.com This e-mail address is being protected from spambots. You need JavaScript enabled to view it)
Related News: Toxics

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RE: NEWS UPDATES: Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review (Risk Policy Report)

Zeise, Lauren@OEHHA to: Kate Guyton 05/23/2012 12:53 PM

Oh my.

From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Tuesday, May 22, 2012 9:21 AM
To: Daniel Axelrad; Zeise, Lauren@OEHHA; woodrufft@obgyn.ucsf.edu
Subject: Fw: NEWS UPDATES: Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review (Risk Policy Report)

FYI....

----- Forwarded by Kate Guyton/DC/USEPA/US on 05/22/2012 12:20 PM -----

Industry Urges EPA To Craft 'Evidence' Guide Ahead Of NAS' IRIS Review

Posted: May 21, 2012

Industry is urging EPA to move ahead with adopting a weight-of-evidence guidance to address data quality concerns in its risk assessment program and not wait for the National Academy of Sciences (NAS) to address the issue in its recently announced review of the Integrated Risk Information System (IRIS) program.

"We are already dismayed it has been more than a year" since NAS urged EPA, as part of its review of the agency's draft formaldehyde assessment, to use some sort of weight-of-evidence analysis when determining which studies it will base its assessment on, an industry source says. While EPA has made steps to adopt some of the changes in that report, the agency "has really done not much at all in this area."

"It's not like they have to wait and develop new guidance," the source adds. "There are plenty of examples out there on how to do weight of evidence appropriately."

The industry calls for EPA to develop guidance comes as the agency May 16 announced that the NAS will review the program, with recommendations expected in two years.

Academy officials proposed to conduct the review in lieu of reviewing two chemical assessments that Congress had originally sought. The NAS panel will "be charged to assess the scientific, technical, and process changes being implemented by EPA for IRIS," an NAS spokesman says (*Risk Policy Report* , May 1).

However, the NAS panel still plans to review the agency's pending assessment for inorganic arsenic, as lawmakers had called for in the agency's fiscal year 2012 spending bill, though EPA appears to have pulled its draft cancer assessment of the substance, according to its IRISTrack website.

In a statement announcing the NAS review, EPA said the academy "will also review current

methods for weight of evidence analysis and recommend approaches for weighing scientific evidence for chemical hazard identification," among many other issues.

Top EPA officials have long indicated that they are considering plans for how to weigh scientific evidence when assessing chemicals but fear that use of such a framework could lead to further delays in a program often maligned for taking too long in producing IRIS assessments (*Risk Policy Report* , Nov. 1).

While industry has long called for weight-of-evidence analyses as part of IRIS assessments, EPA has failed thus far to institute any such practice into the process. In a report to Congress in April on the progress of IRIS reforms, the agency said it will craft weight-of-evidence guidelines in phase 3 of changes to the program, and will "approach or develop a new approach to consistently evaluate weight-of-evidence in IRIS assessments. EPA also will further work to develop systematic approaches to quantify uncertainty and variation." The agency is currently in phase 2 of the process, according to the report.

However, the industry source says without a data quality analysis, EPA cannot ensure the highest quality studies are being used as the basis for risk assessments, and waiting until the NAS finishes its review could mean as many as 50 assessments are released by the time the agency fixes the problem.

"There are ways to move forward with [guidelines] rather quickly, including methodologies" that have already been developed and tested by other groups, the source says. Such methods could be used in weighing data for assessments "without too much effort for EPA to move forward and put them in place pretty quickly . . . I don't think there is a lot of research and development necessary to implement these improvements."

Until such standards are in place, assessments will continue to suffer from data quality issues, the source continues, and while the program should not come to a halt, "we think all assessments need to be held up until they meet the mark." -- *Jenny Hopkinson*

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NEWS UPDATES: Former EPA Scientist Urges Revised Risk Process To Stem Concerns (Inside EPA)
Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew
03/27/2012 09:11 AM

Former EPA Scientist Urges Revised Risk Process To Stem Concerns

Posted: March 26, 2012

A former EPA toxicologist is calling on the agency to revise its risk assessment process for crafting its influential Integrated Risk Information System (IRIS) assessments in order to address concerns from inside the agency that it is unresponsive to the needs of other program offices.

Michael Dourson, now head of a non-profit consulting group, Toxicology Excellence for Risk Assessment (TERA), is calling on the agency's Science Advisory Board (SAB) to include in its pending report on science integration and decisions a recommendation that EPA convene a consensus-based work group of representatives from all of the agency's program offices to resolve issues with IRIS.

Dourson's remarks follow months of criticism of IRIS from Republicans and industry representatives arguing that IRIS assessments are too conservative and lead to unnecessarily stringent regulations. Many agency decisions are based in part on risk assessments, and the IRIS assessments are considered the agency's gold standard analyses. Dourson's remarks, however, hint at concerns within the agency regarding the IRIS program. Dourson worked at the agency when the modern IRIS program was created, and was involved with some of its early assessments.

"[Re-form] the IRIS consensus work groups, force unanimous consensus as it used to be done and bring every agency office to that table," said Dourson, who participated in the first consensus group. "Believe me it will be very painful to do this again and there will be a lot of angst within the offices and a lot of push back, but that will solve the problem . . . because all these people will be at the table and their voices heard and everything."

The change should be part of a broader package of recommendations that the SAB is preparing to issue to EPA on how to encourage science integration for decision making, Dourson said at a meeting of the chartered SAB in Washington, DC, March 22. "We are missing an opportunity to be more expansive," he added.

Dourson's remarks at the SAB meeting followed the Board's discussion over whether to complete its report on science integration for decision making. SAB is preparing to release its recommendations on a project that grew from an unofficial request from then out-going Bush-era EPA Administrator Steve Johnson (*see related story*).

Dourson argued that existing programs at the agency already focus on integrating science in agency decisions, and as such those programs should be fostered and encouraged, especially given that agency and federal policies may prevent greater integration elsewhere. He named IRIS, the Science Technology & Policy Council and the Risk Assessment Forum, as three parts of EPA that already integrate science across the agency.

"EPA has policy silos based on congressional legislation," Dourson said. "You're not going to change these policy silos."

Dourson's arguments differ significantly from recent calls for reforming the IRIS program, which has in recent months been a favorite target of industry and Republican lawmakers who have raised concerns about the transparency of the process and the science the agency uses in drafting its assessments.

Those parties have rallied around the criticism of the program, and the roadmap to fix it, that was laid out last year by the National Academy of Sciences (NAS) in its review of the formaldehyde assessment. EPA has undertaken many of those recommendations and is beginning to include them as it works through and releases new assessments.

While industry and lawmakers have called for a myriad of what they call fixes to the program, few have reflected concerns of agency staff. One appears to be that the IRIS process takes too long. For example, officials from the Government Accountability Office (GAO) said last summer that they would look at risk assessments that EPA program offices need but are reluctant to request as part of an audit of IRIS.

David Trimble, head of GAO's Natural Resources and Environment section in July told a congressional panel that the audit would look at the "pent-up backlog," where program offices, such as the Office of Water, have held back on requesting IRIS assessments because of the existing, unfinished assessments in the system (*Risk Policy Report* , July 19).

And program offices have in the past been vocal with their concerns over assessments. In 2009, for example, agency officials raised questions over the just-released IRIS assessment for arsenic, arguing that proposed increase in estimated cancer risk would result in cost-prohibitive and unattainable regulatory standards.

In comments, EPA Region VIII said the draft assessment's treatment of the cancer risks of low-dose exposure could have "disastrous" impacts on the agency's Superfund cleanup, waste management and drinking water programs, while Region X and EPA's Office of Solid Waste & Emergency Response both asked if the study's cancer risk level passed a "reality check" (*Risk Policy Report,* June 9, 2009). --- *Jenny Hopkinson*

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Re: presentation to ATRA group on formaldehyde

Danielle DeVoney to: Barbara Glenn 03/26/2012 12:16 PM
Cc: Kate Guyton

Barbara -

Hi - I think the topics you suggest below would be of interest to the ATRA group.

I believe it would also be useful to speak with Julie Wroble (Region 10). She is a Regional toxicologist and has been a member of this group for several years. She has some specific interest in formaldehyde and we have discussed the FA assessment off and on (I work with her closely on asbestos issues, and see her a few times a years a various meetings). {The ATRA contact also suggested contacting Julie for specifics.}

I can set up a call (maybe early next week) to pick her brain in terms of what would be of interest to the regional risk assessors in addition to what you suggest below.

Danielle

Danielle DeVoney, PhD, DABT, PE
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-----Barbara Glenn/DC/USEPA/US wrote: -----
To: David Bussard/DC/USEPA/US@EPA
From: Barbara Glenn/DC/USEPA/US
Date: 03/21/2012 03:15PM
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA, Devoney.Danielle@epamail.epa.gov
Subject: Re: presentation to ATRA group on formaldehyde

That sounds reasonable. Thanks.

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

David Bussard---03/21/2012 03:14:01 PM---Sounds okay. Let's avoid conclusions about key issues, such as just which hematopoietic tumors we pl

From: David Bussard/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA, Devoney.Danielle@epamail.epa.gov
Date: 03/21/2012 03:14 PM
Subject: Re: presentation to ATRA group on formaldehyde

Sounds okay.

Let's avoid conclusions about key issues, such as just which hematopoietic tumors we plan to model, response re BBDR, any actual numerical values other than if useful to discuss what was in the proposal, etc.. I.e., I don't want something that if it leaked might seem to get ahead of key decisionmaking in EPA.

David

Barbara Glenn---03/21/2012 03:08:43 PM---We'll talk about the NAS panel's comments and our approach to revising. We'll discuss some of the i

From: Barbara Glenn/DC/USEPA/US
To: David Bussard/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA
Date: 03/21/2012 03:08 PM
Subject: Re: presentation to ATRA group on formaldehyde

We'll talk about the NAS panel's comments and our approach to revising. We'll discuss some of the interesting issues with regard to formaldehyde and risk assessment like measuring formaldehyde in exhaled breath, systemic effects versus systemic delivery, transparency etc.

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David Bussard---03/21/2012 01:56:34 PM---It seems premature to discuss conclusions as to responses to peer review comments. So, what will you

From: David Bussard/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA
Date: 03/21/2012 01:56 PM
Subject: Re: presentation to ATRA group on formaldehyde

It seems premature to discuss conclusions as to responses to peer review comments.

So, what will you cover?

David

Barbara Glenn---03/21/2012 11:18:15 AM---Hi David, I forgot to tell you when Tom and I met with you last week that I was asked by Brook Madro

From: Barbara Glenn/DC/USEPA/US
To: David Bussard/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA
Date: 03/21/2012 11:18 AM
Subject: presentation to ATRA group on formaldehyde

Hi David,
I forgot to tell you when Tom and I met with you last week that I was asked by Brook Madrone for the Air Toxics Risk Assessors group (with participants from regional offices and programs, primarily air) to discuss the formaldehyde assessment and revision with them during their meeting on April 12th. This would be a webinar type format. So Danielle and I agreed to do this with them. Let me know if this is a problem.

-Barbara

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Fw: NEWS UPDATES: EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies (Inside EPA)

Kate Guyton to: Ambuja Bale, Barbara Glenn, Cheryl Scott, Glinda Cooper, Maureen Gwinn, Karen Hogan, Leonid Kopylev, Ravi Subramaniam, Stan

03/20/2012 10:04 AM

EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies

Posted: March 19, 2012

EPA efforts to reform its controversial Integrated Risk Information System (IRIS) program is winning cautious praise from some federal agencies that have strongly criticized the program, which could bolster EPA efforts to defend the program as it prepares to submit an upcoming report on the issue to lawmakers.

"EPA is doing an impressive amount of work" on IRIS and the program "is looking better," as a result, says a source with one federal agency that has levied criticism in the past. "I'm surprised EPA is able to do as much as they're doing with the resources they have," the source adds.

And Kevin Bromberg, of Small Business Administration's (SBA) Office of Advocacy, told attendees at the chemical industry conference GlobalChem in Baltimore March 6 that that it "looks like we're seeing substantial progress and improvements" in the IRIS program. "We're cautiously optimistic," Bromberg said, citing EPA's recent assessments of perchloroethylene (perc) and tetrahydrofuran (THF) as examples of the positive improvements.

In a March 14 letter to Lek Kadeli, the acting head of EPA's Office of Research and Development (ORD), SBA also praised the agency's recent decision to delay its assessment on hexavalent chromium (Cr6) so it can weigh new industry studies that cast doubt on the agency's draft assessment.

"EPA's actions will enhance the scientific integrity of this review and will help to increase confidence in the IRIS program more generally," the letter says. SBA "is pleased that EPA is taking seriously its commitment to rigorous independent expert peer review as well as its commitment to using the best available science." *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2393515)

Several federal agencies -- especially those like the Department of Defense and NASA that could face greater cleanup liability as a result of new risk assessments -- have strongly criticized EPA's IRIS assessments for being overly conservative and lacking scientific basis. In 2010, several federal agencies raised concerns that the Obama administration's revised process for crafting the assessments limited their roles and review times (*Risk Policy Report* , May 11, 2010).

Since then, pressure has grown on EPA to revise its IRIS assessment process after the National Academy of Sciences (NAS) strongly criticized the agency's draft formaldehyde assessment and recommended the agency make a host of additional reforms.

EPA has adopted some additional steps to reform the program -- including creation of a standing scientific panel to review its draft assessments -- and is also crafting others to comply with NAS recommendations, such as an upcoming weight of evidence framework to use in drafting the assessments.

But Congress, in EPA's fiscal year 2012 budget, also required EPA to submit as many as three additional draft assessments, including its arsenic assessment, to NAS for review, rather than review by agency Science Advisory Board or a contractor-created expert panels -- options EPA generally prefers.

Lawmakers also required EPA to detail how each of the assessments it releases in FY12 meets the NAS recommendations, and requests a report from EPA on how it is progressing with the NAS reforms by March 1.

While EPA has not yet submitted the report to Congress, a draft version is under review by other agencies. "As requested in the report language for the Consolidated Appropriations Act of 2012, EPA has prepared an IRIS progress report to Congress," an EPA spokeswoman says. "This report is currently undergoing review and will be sent to Congress as soon as it completes that review."

But with SBA's Bromberg and others praising the reforms EPA has made so far, the interagency review could result in a favorable report to Congress.

The agency source says EPA's upcoming report to Congress is optimistic and praised the changes EPA is already implementing. The source especially welcomed EPA efforts to make its assessments more accessible. "I give them a lot of credit for the [new evidence] tables, making [new IRIS documents] concise," the source says. The source adds that another reform expected to begin this summer, of providing an early discussion session with stakeholders on key scientific issues before beginning to draft assessments "could be critical. EPA will be very much informed."

In his remarks to GlobalChem, Bromber was especially pleased with EPA's recent perc and THF assessments. He noted that with the perc assessment, "EPA changed the endpoint evaluation consistent with peer reviewer recommendations." With THF, Bromberg praised EPA's decision not to calculate a cancer risk estimate because of the uncertainty of its evidence -- a conclusion that Bromberg said EPA should have made with arsenic.

In the THF assessment, EPA "basically said, 'We're not going to do what we did with arsenic. The risk [calculation] would be too high," Bromberg added.

Meanwhile, David Fischer of the American Chemistry Council (ACC) told GlobalChem that the

industry group will soon release a set of principles for IRIS improvement, building off the NAS recommendations as well as those from a recent Government Accountability Office (GAO) report.

According to Fischer's presentation, these principles will include recommendations urging EPA to "fully incorporate the NAS recommendations, rely on the best available science and enable a more complete risk characterization." His slides also indicate the recommendations will state that "EPA must adopt a weight of evidence approach"; "EPA should improve the scientific peer review processes of IRIS assessments" and "NAS should peer review five draft IRIS assessments annually to verify IRIS improvements."

After his remarks, Fischer said that the ACC recommendations will "expand on NAS" recommendations, particularly with regard to peer review of IRIS assessments, which NAS did not address.

Vincent Cogliano, acting director of the IRIS program, told the panel that EPA is "already implementing the recommendations David Fischer shared. But it takes a long time to develop an assessment, so you haven't seen all the fruits of our labor yet." Cogliano outlined the reforms underway intended to respond to the NAS and GAO recommendations.

But Cogliano said IRIS should not routinely be going to NAS for review of IRIS assessments. "I'm a little too humble to say IRIS [assessments] should go to NAS review. NAS should be dealing with really high level scientific issues," he added, suggesting that IRIS assessments do not meet that criteria, and are simply reviews of chemicals' toxicity. -- *Maria Hegstad*

Industry, advocacy groups spar over IRIS as EPA meeting draws crowd (Greenwire)

Kathleen Deener to: Kenneth Olden, Debra Walsh, John Vandenberg, Lynn Flowers, Vincent Cogliano, Karen Hammerstrom, Samantha

11/14/2012 01:32 PM

Cc: Elizabeth Blackburn, Carolyn Hubbard, David Piantanida, Megan Maguire

Industry, advocacy groups spar over IRIS as EPA meeting draws crowd

Jeremy P. Jacobs, E&E reporter

Published: Wednesday, November 14, 2012

U.S. EPA's first-ever fully public meeting on its program for testing chemicals for health hazards turned testy yesterday, as public-health advocates lobbed criticisms at industry groups that quickly sought to defend themselves.

At issue is EPA's Integrated Risk Information System, or IRIS, which is charged with drafting health assessments for chemicals and other environmental pollutants. IRIS's reports are the foundation of EPA and state regulations such as cleanup remediation goals and drinking water standards.

The program has long been beset by problems, but EPA is seeking to implement reforms. Part of that process was hosting a public meeting and webinar yesterday that drew more than 400 participants in person and online.

"The best way to deal with complex issues -- whether they be scientific or otherwise -- is through public dialogue and transparency," said Kenneth Olden, director of EPA's National Center for Environmental Assessment, which oversees IRIS. "We need your help. We need your advice and your support."

Public health advocates provided advice: Industry, they said, routinely undermines IRIS by seeking to delay assessments at every opportunity available. And IRIS's backlog of assessments, thought to be hundreds if not thousands of chemicals, has been repeatedly criticized by watchdogs like the Government Accountability Office.

Richard Denison of the Environmental Defense Fund said IRIS is wildly out of balance. He said industry has a financial interest in preventing IRIS assessments from being completed. Consequently, it will always be more organized when it comes to providing public comments, peer review or more data to delay finalization.

The result, Denison said, is a system that benefits industry at the expense of the public.

"IRIS has repeatedly allowed the demands for more and more data to indefinitely delay its assessments," Denison said. "We simply must stop pretending that there is a level playing field."

Denison noted that EPA has a long-held goal of finishing an assessment in 23 months, but not a single one has met that deadline. The average complete rate has been seven-and-a-half years.

He then proposed that EPA reform IRIS to provide fewer, instead of more, opportunities for public comment -- something that flies in the face of both industry's position and EPA's proposed revisions.

"I know this playing field isn't level," said Vincent Cogliano, IRIS's acting director. "But I don't want to go backward and say we're going to shut the door and say we'll have less engagement."

David Fischer of the American Chemistry Council defended the industry. He acknowledged that EPA has made some changes ACC supports, but he said the peer review process must be improved.

EPA, he said, needs to allow "sufficient time for the public to provide input to peer reviewers ... and to allow a dialogue with peer reviewers."

Further, he emphasized that the root of ACC's concerns is for IRIS's foundation to be transparent and solid science.

"Let's make sure we get as much out of that peer review process as possible," he said. And "ensure that EPA has really taken a hard look at what the peer reviewer has articulated in their report."

That is essential, he said, to make sure "as much value of that investment in the peer review process is garnered by the agency."

But Linda Birnbaum, director of the National Institutes of Health's National Institute of Environmental Health Sciences, said those remarks underscore industry's skepticism of EPA science.

"Frankly, I think when people serve on peer review panels, they usually spend a lot of time looking at information provided to them," she said. "But I think what it really shows is the complete breakdown of trust throughout this whole process."

Denison went a step farther.

"Frankly, it's [an] assault on independent government science," he said.

Formaldehyde assessment spurred critics

In a follow-up interview, Fischer said EPA's proposal to add a public meeting before a draft has

begun may be viewed as another step in the process, but it shouldn't delay the assessments. Instead, it could speed them up.

"If that's considered another step, I guess it is, but it may actually tend to shorten the time frame," he said.

Denison also criticized industry for repeatedly calling for a National Academy of Sciences review of all IRIS draft assessments -- something he said would add years to the process and cost millions of dollars, and is an example of another dilatory tactic. ACC called for such a requirement last year.

Scott Jensen, a spokesman for ACC, said the group has since changed that position in light of EPA's improvements.

"I don't think anybody is calling for an NAS review of all draft assessments," he said.

EPA's IRIS program has long been criticized by public health and industry groups. But industry became extremely vocal on the issue when an NAS review of IRIS's assessment of formaldehyde, a common ingredient in household construction materials, found major problems with the program's methodologies and recommended changes last year (*Greenwire* , April 8, 2011).

The agency has since said it is implementing every one of the NAS panel's suggestions, though industry has remained concerned about the pace of those improvements (*E&ENews PM* , July 12, 2011).

In particular, ACC has argued that EPA has yet to articulate an adequate weight of evidence approach for how it selects studies and which studies it relies on more in its assessments.

"It's unclear to us how EPA has applied a weight of evidence framework in reaching its causality conclusions," Fischer said. "It is unclear to us, [and] it is something EPA needs to address."

The acrimonious public underscores that EPA's IRIS program, and its reforms, will remain a hot topic among interested stakeholders, including lawmakers on Capitol Hill.

House Republicans inserted a measure in last year's omnibus spending measure that required NAS to conduct a broad review of IRIS, which it recently began (*Greenwire* , Sept. 18).

Further, EPA's inspector general has also launched a review of IRIS, also at the behest of a Republican lawmaker (*E&E Daily* , March 9).

Perhaps because of that magnifying glass, Cogliano sought to emphasize improvements EPA has made to ensure transparency, even if they do not satisfy Denison's criteria.

"We're improving the process through early public engagement," he said. "We hope that by engaging stakeholders early, we will put all the issues on the table, we will avoid late hits, and

we will [create] an outcome that everyone can respect."

Kacee Deener, MPH

Director, Communications and Regulatory Support Team

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NEWS UPDATES: EPA IG To Review Agency's Use Of IRIS Assessments In Decision Making (Inside EPA)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

03/09/2012 03:35 PM

EPA IG To Review Agency's Use Of IRIS Assessments In Decision Making

Posted: March 9, 2012

EPA's Office of Inspector General (IG) is launching an investigation into how agency program and regional offices utilize the influential toxicological assessments prepared by the agency's Integrated Risk Information System (IRIS), the controversial program that has drawn widespread criticism from industry groups and GOP lawmakers.

The office March 7 released a memo to Lek Kadeli, the acting chief of EPA's research office, informing him that the IG is beginning a review to "determine which EPA offices and regions utilize data derived from IRIS assessments or other similar systems" and "determine how EPA offices and regions utilize data derived from IRIS assessments, and the circumstances under which they use IRIS or an alternate system."

The March 2 memo indicates that the review was initiated in response to a request from Rep. Paul Broun (R-GA), who chairs the House science committee's oversight panel, which oversees EPA's research office.

The IRIS program was begun in the mid-1980s to provide continuity for EPA program and regional offices making decisions about how to deal with environmental problems. The program's hazard assessments have become an authoritative source for new water, air or cleanup regulations, though it is often faulted for its slow turnaround.

During the George W. Bush administration, the Government Accountability Office (GAO) listed IRIS as a "high risk" program due to its inability to complete assessments in a timely fashion.

But the assessments' influence has led to increasing controversy in recent years, with affected industries and other federal agencies often complaining that the assessments are overly conservative and lacking in scientific foundation. The controversy crescendoed when a National Academy of Sciences (NAS) panel faulted the agency's draft assessment of formaldehyde and reiterated a host of program reforms contained in earlier NAS recommendations.

Since taking office, Obama administration officials have made several changes to the program in an effort to increase its transparency and speed assessments, though officials are implementing additional reforms to address NAS and GAO concerns.

Simultaneously, the agency has completed several high-profile assessments over the past few

months, including long-awaited analyses of the risks posed by dioxin, the dry-cleaning solvent perchloroethylene (perc) and the industrial solvent tetrachloroethylene (TCE).

Nevertheless, Congress has sought additional oversight and is requiring the agency to subject up to three more pending assessments to NAS review. Among the lawmakers concerned about the program, several House science committee panels have held hearings over the past year on the quality of EPA science, including the IRIS program.

The IG's review is intended "to further inform this oversight," Broun said in a Feb. 23 letter to IG Arthur Elkins. "It would be helpful to understand the extent that EPA offices and regions use IRIS data to estimate and manage risk. Similarly, it would also be helpful to understand whether program offices and regions use assessments from other sources for their work, or whether they conduct their own assessments. Understanding how agency offices and regions develop and utilize assessments would provide insight into whether duplication or inefficiencies exist."

The memo notes that EPA's IRIS program has undergone review by the oversight committee "in recent years." Most of these IRIS-specific hearings were held under then-Chairman Brad Miller (D-NC) in 2008 and 2009, where the Bush EPA's circuitous process for creating IRIS assessments was blamed for the lengthy delays in publishing assessments. That process was replaced with a much more streamlined version shortly after Administrator Lisa Jackson took office.

Broun also noted reports from GAO in 2008 and 2011 that raised concerns with the program, as well as the NAS' critical review of the program in its April 2011 review of the agency's formaldehyde assessment.

Among other things, Broun asked the IG to investigate which EPA offices and regions utilize the cancer and non-cancer effects data derived from IRIS assessments, and what they use it for; if offices do not use IRIS values, or only use them intermittently, what drives their decisions; how frequently are values other than IRIS values incorporated into offices' final products; what risk values do they use "instead of, or in addition to" IRIS values; "under what circumstances do EPA program offices and regions develop their own values;" and "are assessments conducted in place of an IRIS value, or only if an IRIS value does not exist."

Broun requests the work be completed by September. – *Maria Hegstad*

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NEWS UPDATES: EPA Tells Congress About IRIS Reforms ; Two Assessments Coming in Summer (BNA)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

05/07/2012 11:40 AM

EPA Tells Congress About IRIS Reforms ; Two Assessments Coming in Summer

By Pat Rizzuto

Draft Integrated Risk Information System (IRIS) assessments for ammonia and two trimethylbenzenes will be sent for peer review by a new Science Advisory Board committee this summer, the Environmental Protection Agency told legislators in a congressionally mandated report.

The assessments will use a new document structure the agency is developing as part of its response to recommendations from the National Academies' National Research Council, the agency said in the report, EPA's Integrated Risk Information System Program: Progress Report and Report to Congress.

The Consolidated Appropriations Act of 2012 (Pub. Law 112-74) directed the agency to issue a report by March 1 to the House and Senate appropriations committees describing the agency's implementation of Research Council recommendations. The law referred specifically to recommendations the council made in a critique of EPA's draft IRIS assessment of formaldehyde (69 DEN A-1, 4/11/11)

EPA sent the report to Congress on April 23.

Structural, Other Changes

The document describes ways the agency intends to make IRIS assessments shorter and easier to read. It also briefed legislators on:

• ways the agency plans to help the public understand its rationale for selecting some studies for inclusion in the assessment and excluding others;
• a workshop it plans to hold to discuss approaches it could use to weigh evidence about toxicity of a chemical;
• consultations it will host to increase the public's opportunities to participate in the formation of IRIS assessments; and
• a new SAB committee the agency is forming to offer consistent peer review of IRIS documents.

Many Changes Already Discussed

EPA officials already have discussed at public meetings many of the changes described in the report to Congress (22 DEN A-8, 2/3/12).

At meetings BNA attended, however, agency officials had not announced which IRIS assessments would be the first to be reviewed by SAB's new IRIS advisory committee.
Paul Anastas, former EPA assistant administrator for research and development, announced plans for that committee in July (134 DEN A-7, 7/13/11).

The committee, called the SAB Chemical Assessment Advisory Committee, is still being formed and has not scheduled its first meeting, the designated EPA official for the committee told BNA May 3.

Public Comment to Be Sought

EPA's congressional report said the first draft IRIS assessments the agency will submit to that committee

will analyze the toxicity of ammonia and 1,2,4-trimethylbenzene along with 1,3,5-trimethylbenzene. The draft assessments also will be released for public comment, the agency said.

Ammonia was produced in volumes of 1 billion pounds or more in the United States in 2006, according to EPA. It is a naturally occurring as well as synthetically produced chemical used for products, including household and industrial cleaners and fertilizers.

Trimethylbenzenes occur in coal tar and petroleum, according to EPA. It said more than 80 billion pounds were produced in 1991 and used in dyes, solvents, paint thinners, and other chemicals.
EPA will release its report on IRIS to the public during the first week of June, the agency told BNA.

Industry Says Formatting Changes Not Enough

The American Chemistry Council, which represents major U.S. chemical manufacturers, has seen EPA's report and provided a statement to BNA.

“It's clear the EPA continues to fall short of following the direction of Congress to make the improvements needed to ensure IRIS delivers clear and objective assessments based on sound science,” the council said.

“Until such improvements are made, the program will continue to produce assessments that create unnecessary confusion and fail to properly guide public health decisions.
“Simply reformatting and rearranging the layout of the assessments to include more figures and tables and less text, as EPA intends to do, will not address the most critical areas of improvement that were identified by the National Academies.

“We have deep concerns that the entire generation of draft, and final IRIS assessments, that have been or will be issued this year, will suffer from many of the very same critical scientific shortcomings that plagued the draft formaldehyde assessment.”

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NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

06/12/2012 09:35 AM

History: This message has been forwarded.

EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion

Posted: June 11, 2012

EPA scientists are examining molecular data for several chemicals undergoing risk assessments in efforts to further understand how these newer types of information can inform agency analyses as part of the agency's ongoing effort to transition to the "next generation" (NexGen) of risk assessment, including both these data and traditional toxicology.

Agency scientists hope to use the data to further inform the ongoing Integrated Risk Information System (IRIS) assessments for five high-interest chemicals -- benzo(a)pyrene (BaP), chloroform, arsenic, hexavalent chromium (Cr6) and formaldehyde -- said Ila Cote, senior science adviser to the Immediate Office of the Director the National Center for Environmental Assessment. Depending on the amount and quality of the data available, Cote said, risk assessors may be able to incorporate the information into the IRIS assessments to varying degrees.

But Cote warned that she didn't want to "overpromise" on what the effort could deliver because it is still unclear how much molecular data there are for each of the five chemicals and their quality. Cote spoke at a May 30 meeting of a Science Advisory Board (SAB) committee charged with advising EPA on how to incorporate new computational toxicology methods into risk assessment. *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2401405)

EPA's NexGen program seeks to determine how to incorporate newer computational and systems biology approaches into risk assessment. It also seeks to create a tiered approach that requires greater burdens of evidence on assessments for higher-priority chemicals. As part of the effort the agency is seeking to identify chemicals with a wealth of data available and "reverse engineer" prototypes from them, and create decision rules for using the newer types of data into risk assessments.

With thousands of chemicals in commerce for which EPA does not have toxicity testing results, the agency is grappling with how to speed up chemical risk assessments to get more chemicals tested. At the same time, EPA must ensure that the new molecular, cellular and computational methods can accurately supplement, or in some cases replace, existing animal-based *in vivo* methods that are seen by many as costly and time-consuming.

Cote's presentation identifies the five chemicals as part of the highest of the NexGen framework's three tiers, which is reserved for those chemicals that come with "nationwide exposure and nationwide risk," Cote said at the meeting. Tier III chemicals, according to the presentations, can draw on all "policy-relevant" data ranging from high-throughput to low-throughput and from molecular to macroscopic-level, but the resulting risk assessments also come with the highest burden of evidence given the priority assigned to the chemical, according to the presentation.

EPA has been working on "proof of concept" prototypes on three chemicals -- polycyclic aromatic hydrocarbons (PAHs), benzene and ozone. The agency hopes to "extend what is learned to [Tier III] chemicals with less data," according to the presentation. Another benefit EPA hadn't initially predicted, Cote said, is that the agency can use what is learned to help resolve issues with chemicals for which questions remains despite a wealth of traditional data existing.

Cote did not explain how extensively the data might influence the final risk assessments, as the agency is still evaluating the data. But she emphasized that "in all of these there will be a peer-review process of what we've done and opportunity to engage in scientific community and refine these processes as we move forward."

Cote said EPA would seek to finish assessing the BaP microscopic data in June 2012 which would come before the agency's projected fourth-quarter fiscal year 2012 release of a draft reassessment for public comment and peer review. The assessment would serve to update a 1994 analysis of BaP, one of the most well-known PAHs, the ubiquitous class of chemicals that are formed from incomplete combustion of wood, fossil fuels and food and are

found in crude oil, asphalt, vehicle emissions and other sources (*see related story*).

The BaP assessment would be of special importance because a SAB panel asked the agency in 2010 to finish the BaP update assessment before finalizing guidance on determining carcinogenicities of other PAHs by using BaP as an index chemical through a relative potency factor approach. An agency source tells *Inside EPA* that studying the BaP molecular data probably will not delay the BaP cancer assessment update.

It was not immediately clear how the microscopic-level data would influence the final IRIS assessment of formaldehyde, a chemical for which the draft assessment came under fire from industry and a peer-review panel at the National Academy of Sciences. The EPA presentation says the agency expects to finish the NexGen information for the formaldehyde assessment by February 2013, with the assessment's release for peer review occurring as early as the third quarter of fiscal year 2013.

Industry, meanwhile, has sought to convince EPA that the carcinogenicity of Cr6 -- the particular form of chromium EPA is assessing -- does not occur mutagenically but instead through different a mode of action (MoA) that would not require EPA to use a linear low-dose extrapolation that generally produces stricter risk values. The EPA presentation says the agency will finish studying and assembling the Cr6 molecular data by 2013. EPA's website lists the oral and inhalation IRIS assessment, which it delayed to consider the industry's claims on the MoA, as due out for peer review and public comment also in 2013.

The agency plans to finish studying and potentially assemble the data on chloroform by December 2012 and on arsenic by 2014, according to the presentation. -- *Puneet Kollipara*

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Fw: NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)

Kate Guyton to: Rusyn Ivan I 06/12/2012 01:28 PM

-----Forwarded by Kate Guyton/DC/USEPA/US on 06/12/2012 01:26PM -----

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Posted: June 11, 2012

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Re: presentation to ATRA group on formaldehyde

Barbara Glenn to: Danielle DeVoney 03/26/2012 12:35 PM
Cc: Kate Guyton

I agree if would be helpful to talk with Julie. Thanks for offering to arrange a call. -Barbara

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

Danielle DeVoney Barbara - Hi - I think the topics you suggest belo... 03/26/2012 12:15:59 PM

From: Danielle DeVoney/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Kate Guyton/DC/USEPA/US@EPA
Date: 03/26/2012 12:15 PM
Subject: Re: presentation to ATRA group on formaldehyde

Barbara -

Hi - I think the topics you suggest below would be of interest to the ATRA group.

I believe it would also be useful to speak with Julie Wroble (Region 10). She is a Regional toxicologist and has been a member of this group for several years. She has some specific interest in formaldehyde and we have discussed the FA assessment off and on (I work with her closely on asbestos issues, and see her a few times a years a various meetings). {The ATRA contact also suggested contacting Julie for specifics.}

I can set up a call (maybe early next week) to pick her brain in terms of what would be of interest to the regional risk assessors in addition to what you suggest below.

Danielle

Danielle DeVoney, PhD, DABT, PE
National Center for Environmental Assessment
USEPA Office of Research and Development
1200 Pennsylvania Ave., NW (8623P)
Washington, DC 20460
703.347.8558
FAX: 703.347.8692

-----Barbara Glenn/DC/USEPA/US wrote: -----
To: David Bussard/DC/USEPA/US@EPA
From: Barbara Glenn/DC/USEPA/US
Date: 03/21/2012 03:15PM
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA, Devoney.Danielle@epamail.epa.gov
Subject: Re: presentation to ATRA group on formaldehyde

That sounds reasonable. Thanks.

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

David Bussard---03/21/2012 03:14:01 PM---Sounds okay. Let's avoid conclusions about key issues, such as just which hematopoietic tumors we pl

From: David Bussard/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA, Devoney.Danielle@epamail.epa.gov
Date: 03/21/2012 03:14 PM
Subject: Re: presentation to ATRA group on formaldehyde

Sounds okay.

Let's avoid conclusions about key issues, such as just which hematopoietic tumors we plan to model, response re BBDR, any actual numerical values other than if useful to discuss what was in the proposal, etc.. I.e., I don't want something that if it leaked might seem to get ahead of key decisionmaking in EPA.

David

Barbara Glenn---03/21/2012 03:08:43 PM---We'll talk about the NAS panel's comments and our approach to revising. We'll discuss some of the i

From: Barbara Glenn/DC/USEPA/US
To: David Bussard/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA
Date: 03/21/2012 03:08 PM
Subject: Re: presentation to ATRA group on formaldehyde

We'll talk about the NAS panel's comments and our approach to revising. We'll discuss some of the interesting issues with regard to formaldehyde and risk assessment like measuring formaldehyde in exhaled breath, systemic effects versus systemic delivery, transparency etc.

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

David Bussard---03/21/2012 01:56:34 PM---It seems premature to discuss conclusions as to responses to peer review comments. So, what will you

From: David Bussard/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Charles Ris/DC/USEPA/US@EPA
Date: 03/21/2012 01:56 PM
Subject: Re: presentation to ATRA group on formaldehyde

It seems premature to discuss conclusions as to responses to peer review comments.

So, what will you cover?

David

Barbara Glenn---03/21/2012 11:18:15 AM---Hi David, I forgot to tell you when Tom and I met with you last week that I was asked by Brook Madro

From: Barbara Glenn/DC/USEPA/US
To: David Bussard/DC/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA
Date: 03/21/2012 11:18 AM
Subject: presentation to ATRA group on formaldehyde

Hi David,
I forgot to tell you when Tom and I met with you last week that I was asked by Brook Madrone for the Air Toxics Risk Assessors group (with participants from regional offices and programs, primarily air) to discuss the formaldehyde assessment and revision with them during their meeting on April 12th. This would be a webinar type format. So Danielle and I agreed to do this with them. Let me know if this is a problem.

-Barbara

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
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NEWS UPDATE: EPA Weighs Industry Request To Expand Petrochemical Risk Assessment (Inside EPA)
Dahnish Shams to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew
08/07/2012 03:15 PM

Risk Policy Report - 08/07/2012

EPA Weighs Industry Request To Expand Petrochemical Risk Assessment

Posted: August 6, 2012

EPA will weigh a chemical industry push for the agency to expand its draft risk assessment of three isomers of trimethylbenzenes (TMBs) found in petroleum and engine exhaust, an EPA source says, with industry seeking the inclusion of additional related chemicals in the study to provide more accurate data on the TMBs' toxicities.

"The data sets they left out are essential to understanding . . . the potential toxicities," Richard Becker, a senior toxicologist at the American Chemistry Council (ACC), said at an Aug. 1 EPA listening session on the Integrated Risk Information System (IRIS) study for the isomers 1,2,3-TMB, 1,2,4-TMB and 1,3,5-TMB. "It falls short in what's needed in an IRIS assessment. The quality and reliability [of the additional data sets] is very high," he said.

Richard McKee, an ExxonMobil scientist speaking for ACC, said the assessment excludes data on several ethyltoluenes -- chemicals that are part of the C9 aromatic hydrocarbon group of compounds that includes TMBs.

An agency source says IRIS staff will "have to look at exactly what" EPA's Office of Pollution, Prevention and Toxics (OPPT) did with the draft risk assessment "and talk with [IRIS] users in the agency" before determining whether to include the additional information and chemicals in the TMB assessment. If EPA expands the study to include the extra data, it would not be the first time it has done so. A previous draft of the assessment, circulated among interested federal agencies, included only two of the three TMB isomers. The third, 1,2,3-TMB, was added following questions from several agencies recommending EPA include it to the assessment (*Risk Policy Report* , July 3).

EPA June 26 released the draft study, saying the TMBs are "produced during petroleum refining and production of aromatic hydrocarbons with nine carbons (i.e., C9 aromatic fraction). As the vast majority of the C9 fraction is used as a component of gasoline, vehicle emissions are expected to be the major anthropogenic source of TMBs."

EPA's TMB analyses are based on 1,2,4-TMB, the isomer about which the agency indicated it has the most information. The agency calculated a reference dose (RfD) -- the greatest amount of a substance the agency anticipates can be consumed daily over a lifetime without adverse effects -- of 6x10^-3 milligrams per kilogram-body weight per day (mg/kg-day). The agency calculated

the same RfD for each isomer in the draft risk assessment.

At the listening session, ACC presented information from a publication by Firth et al, published in 2008, based on studies industry performed under a 1985 test rule by OPPT. The Firth publication calculated an RfD of 0.4 mg/kg-day, and a reference concentration (RfC) -- the greatest amount of a substance the agency anticipates can be inhaled daily over a lifetime without adverse effects -- of 3 milligrams per cubic meter of air (mg/m^3).

EPA calculated a stricter RfC of 2x10^-2 mg/m^3. Again, EPA calculated the same RfC for each isomer. *Relevant documents are available on InsideEPA.com. See page for 2 details.* (*Doc ID: 2406616*)

McKee and Becker questioned EPA IRIS staff over their exclusion of the OPPT test rule data. The data was intended to describe the full group of C9 aromatic hydrocarbon compounds, they said. OPPT treated the full group as equivalent for the purposes of toxicity testing, they said, and asked why IRIS staff split the TMBs from the group -- and only considered data about these three isomers equivalent for the purpose of assessment.

Becker noted that the studies were used in the High Production Volume (HPV) Challenge Program that EPA operated during the Clinton and George W. Bush administrations to gather chemical toxicity data voluntarily from industry. He added that they have also been included in data submitted about the chemicals under the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. "The category approach used in HPV and test rules reflects the way the chemicals are used and processed," Becker said.

McKee added, "Some of the studies most useful weren't considered," in the TMBs study. For example, one of the studies dosed animals orally -- a study excluded from the draft IRIS assessment. Using it as the basis for the RfD would be easier, since EPA assessors wouldn't have to perform route-to-route extrapolation from an inhalation study to calculate the oral risk estimate, he said. "I didn't understand the exclusion criteria."

Vincent Cogliano, the acting director of EPA's IRIS program, said in response to the industry comments, "The studies of the C9 aromatic hydrocarbons include trimethylbenzene but also other compounds . . . we were looking at it as a trimethylbenzene assessment. I think that's why [the other studies] weren't included."

McKee acknowledged that the studies assessed the group of chemicals, which are "about 45 percent other things" than TMB. But he argued that OPPT in its request for the testing set the policy of assessing the full group of hydrocarbons together, and he asked why the agency had "changed its policy."

Becker also urged IRIS staff to hasten progress toward fully adopting all of the recommendations the National Academy of Sciences made on overhauling the IRIS program, as part of its critical review of EPA's draft formaldehyde assessment. Becker suggested that EPA "develop a new formal step to design each IRIS assessment."

Becker suggested this design plan could be put out for public review before EPA drafts its IRIS assessments, which would avoid problems such as that seen in the TMB draft, which he said excluded important data.

"It would be a real opportunity for us and other interested stakeholders to say 'Why?' or 'Why not?' instead of now facing a re-do. It would be more time up front, but I think the payoff in the back end would be tremendous," Becker said. He pointed to the situation with the C9 hydrocarbon studies as an example. "OPPT requested these studies. They're referenced in a few lines [in the draft TMB assessment] and then dismissed . . . at a minimum, you should go back and talk with OPPT about the classification of C9 aromatics." -- *Maria Hegstad*

Dahnish Shams
National Center for Environmental Assessment Intern
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Work: (703) 347-0357

RE: NEWS UPDATES: EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies (Inside EPA)
Rusyn, Ivan I to: Kate Guyton 03/20/2012 11:18 AM

Ha, I just sent you the same… ☺

From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Tuesday, March 20, 2012 10:12 AM
To: Rusyn, Ivan I
Subject: Fw: NEWS UPDATES: EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies (Inside EPA)

Perky news! :-)

EPA's IRIS Assessment Reforms Win Cautious Praise From Federal Agencies

Posted: March 19, 2012

EPA efforts to reform its controversial Integrated Risk Information System (IRIS) program is winning cautious praise from some federal agencies that have strongly criticized the program, which could bolster EPA efforts to defend the program as it prepares to submit an upcoming report on the issue to lawmakers.

"EPA is doing an impressive amount of work" on IRIS and the program "is looking better," as a result, says a source with one federal agency that has levied criticism in the past. "I'm surprised EPA is able to do as much as they're doing with the resources they have," the source adds.

And Kevin Bromberg, of Small Business Administration's (SBA) Office of Advocacy, told attendees at the chemical industry conference GlobalChem in Baltimore March 6 that that it "looks like we're seeing substantial progress and improvements" in the IRIS program. "We're cautiously optimistic," Bromberg said, citing EPA's recent assessments of perchloroethylene (perc) and tetrahydrofuran (THF) as examples of the positive improvements.

In a March 14 letter to Lek Kadeli, the acting head of EPA's

Office of Research and Development (ORD), SBA also praised the agency's recent decision to delay its assessment on hexavalent chromium (Cr6) so it can weigh new industry studies that cast doubt on the agency's draft assessment.

"EPA's actions will enhance the scientific integrity of this review and will help to increase confidence in the IRIS program more generally," the letter says. SBA "is pleased that EPA is taking seriously its commitment to rigorous independent expert peer review as well as its commitment to using the best available science." *Relevant documents are available on InsideEPA.com.* (*Doc ID:* *2393515*)

Several federal agencies -- especially those like the Department of Defense and NASA that could face greater cleanup liability as a result of new risk assessments -- have strongly criticized EPA's IRIS assessments for being overly conservative and lacking scientific basis. In 2010, several federal agencies raised concerns that the Obama administration's revised process for crafting the assessments limited their roles and review times (*Risk Policy Report* , May 11, 2010).

Since then, pressure has grown on EPA to revise its IRIS assessment process after the National Academy of Sciences (NAS) strongly criticized the agency's draft formaldehyde assessment and recommended the agency make a host of additional reforms.

EPA has adopted some additional steps to reform the program -- including creation of a standing scientific panel to review its draft assessments -- and is also crafting others to comply with NAS recommendations, such as an upcoming weight of evidence framework to use in drafting the assessments.

But Congress, in EPA's fiscal year 2012 budget, also required EPA to submit as many as three additional draft assessments, including its arsenic assessment, to NAS for review, rather than review by agency Science Advisory Board or a contractor-created expert panels -- options EPA generally prefers.

Lawmakers also required EPA to detail how each of the assessments it releases in FY12 meets the NAS recommendations, and requests a report from EPA on how it is progressing with the NAS reforms by March 1.

While EPA has not yet submitted the report to Congress, a draft version is under review by other agencies. "As requested in the

report language for the Consolidated Appropriations Act of 2012, EPA has prepared an IRIS progress report to Congress," an EPA spokeswoman says. "This report is currently undergoing review and will be sent to Congress as soon as it completes that review."

But with SBA's Bromberg and others praising the reforms EPA has made so far, the interagency review could result in a favorable report to Congress.

The agency source says EPA's upcoming report to Congress is optimistic and praised the changes EPA is already implementing. The source especially welcomed EPA efforts to make its assessments more accessible. "I give them a lot of credit for the [new evidence] tables, making [new IRIS documents] concise," the source says. The source adds that another reform expected to begin this summer, of providing an early discussion session with stakeholders on key scientific issues before beginning to draft assessments "could be critical. EPA will be very much informed."

In his remarks to GlobalChem, Bromber was especially pleased with EPA's recent perc and THF assessments. He noted that with the perc assessment, "EPA changed the endpoint evaluation consistent with peer reviewer recommendations." With THF, Bromberg praised EPA's decision not to calculate a cancer risk estimate because of the uncertainty of its evidence -- a conclusion that Bromberg said EPA should have made with arsenic.

In the THF assessment, EPA "basically said, 'We're not going to do what we did with arsenic. The risk [calculation] would be too high," Bromberg added.

Meanwhile, David Fischer of the American Chemistry Council (ACC) told GlobalChem that the industry group will soon release a set of principles for IRIS improvement, building off the NAS recommendations as well as those from a recent Government Accountability Office (GAO) report.

According to Fischer's presentation, these principles will include recommendations urging EPA to "fully incorporate the NAS recommendations, rely on the best available science and enable a more complete risk characterization." His slides also indicate the recommendations will state that "EPA must adopt a weight of evidence approach"; "EPA should improve the scientific peer review processes of IRIS assessments" and "NAS should peer review five draft IRIS assessments annually to verify IRIS improvements."

After his remarks, Fischer said that the ACC recommendations will "expand on NAS" recommendations, particularly with regard to peer review of IRIS assessments, which NAS did not address.

Vincent Cogliano, acting director of the IRIS program, told the panel that EPA is "already implementing the recommendations David Fischer shared. But it takes a long time to develop an assessment, so you haven't seen all the fruits of our labor yet." Cogliano outlined the reforms underway intended to respond to the NAS and GAO recommendations.

But Cogliano said IRIS should not routinely be going to NAS for review of IRIS assessments. "I'm a little too humble to say IRIS [assessments] should go to NAS review. NAS should be dealing with really high level scientific issues," he added, suggesting that IRIS assessments do not meet that criteria, and are simply reviews of chemicals' toxicity. -- *Maria Hegstad*

FYI

Jane Caldwell to: Cheryl Scott, Weihsueh Chiu, Kate Guyton, Jennifer Jinot 02/08/2012 09:26 AM

----- Forwarded by Jane Caldwell/DC/USEPA/US on 02/08/2012 09:25 AM -----

From: Jane Caldwell/DC/USEPA/US
To: Jane Caldwell/DC/USEPA/US@EPA
Date: 02/08/2012 09:06 AM
Subject:

CHEMICALS:

Industry group boosted political spending last year -- and it paid off

Jeremy P. Jacobs, E&E reporter

Published: Tuesday, February 7, 2012

The American Chemistry Council significantly ramped up its lobbying efforts in the fourth quarter of last year, spending more than double its total for any quarter in recent history.

ACC, the chief lobbying arm of the chemical manufacturing industry, spent $5.37 million in the fourth quarter. The total represents the fifth most of any lobbying operation on Capitol Hill during that period, outspending the perennially deep-pocketed efforts of General Electric Co. and the Pharmaceutical Research and Manufacturers of America, according to a Center for Responsive Politics analysis conducted for *E&E Daily*.

A review of ACC's lobbying disclosure report shows the group was involved in a host of issues, ranging from efforts to update chemical regulations, to U.S. EPA's air pollution rules for boilers and incinerators, to EPA's long-delayed health assessments of substances like bisphenol A (BPA) and formaldehyde. The group also successfully pushed for inserting language into the $1 trillion omnibus spending package passed at the end of the year and aired its first television ads of the election cycle.

The spending is significant because it shows ACC, which public health advocates view as public enemy No. 1, is having an ever-growing role on regulatory and legislative issues.

Anne Kolton, an ACC spokeswoman, said the lobbying shows the group

has a renewed and sharper focus on Capitol Hill.

"The spending is a reflection of our increasingly aggressive approach to advocacy," Kolton said. "Policies that will support economic growth and job creation are very important for the future of our industry."

For all of 2011, ACC spent almost $10.3 million, significantly more than the $8.1 million it spent the year before. Last year's total trumps what was doled out by Dow Chemical Co., the industry's other major lobbying operation, which spent $7.3 million. The American Petroleum Institute, the largest trade association for the oil and gas industry, also spent far less than ACC in 2011 -- less than $6.3 million.

In some cases, the results of ACC's increased spending are crystal clear.

The group was most effective lobbying on the year-end omnibus spending package. Buried in the 1,200-page bill was language that requires EPA's Integrated Risk Information System (IRIS) to implement changes to its scientific methodologies outlined in a National Academy of Sciences review of the agency's formaldehyde risk assessment. It also requires EPA to submit a progress report to Congress by March and stipulates that EPA send three IRIS assessments to NAS for review next year.

ACC has long pushed for IRIS reforms, though critics argue that the group's goal is to delay the agency from finalizing assessments because they are the foundation of new, often stricter, regulations.

Notably, Democrats and some public health advocates touted the IRIS reforms in the omnibus as a compromise, implying that Republicans had sought stronger provisions to handcuff the IRIS program. Public health advocates have also noted that EPA is already in the process of implementing the NAS recommendations (*E&E Daily* <http://www.eenews.net/EEDaily/2011/12/20/archive/3> , Dec. 20, 2011).

Kolton nevertheless called the language a "major victory."

"We saw a lot of success last year," she said. "It is a difficult environment, but we were able to move some key priorities."

The omnibus also contained $1 million to pay NAS for a scientific peer

review of Department of Health and Human Services' "Report on Carcinogens." Last year, the document said styrene -- a common component of plastic food packaging -- is "reasonably anticipated" to cause cancer. The report also said formaldehyde, a common construction material, is a known carcinogen.

Industry has vocally criticized the report, and the styrene industry has sued HHS.

While ACC was clearly successful on the omnibus, the effects of its efforts were felt in other areas as well -- albeit less obviously.

The group criticized Sen. Frank Lautenberg's (D-N.J.) "Safe Chemicals Act" (S. 847 <http://www.eenews.net/bills/112/Senate/090611150815.pdf>), which would overhaul the 1976 Toxic Substances Control Act (TSCA) and require manufacturers to prove their substances are safe before they go on the market. Lautenberg's efforts appear to have stalled late last year after a hearing featuring ACC President Cal Dooley devolved into screaming when Democrats pressed Dooley, a former Democratic congressman, to submit legislative language (*Greenwire* <http://www.eenews.net/Greenwire/2011/11/17/archive/6> , Nov. 17, 2011).

Similarly, ACC's disclosure forms show it lobbied EPA on its 27-year-old IRIS assessment of dioxin, a family of chemicals believed to cause cancer. EPA was supposed to finalize the non-cancer portion of its dioxin assessment in January but missed that deadline in the face of significant industry opposition. The agency has yet to explain what is causing the delay (*Greenwire* <http://www.eenews.net/Greenwire/2012/02/01/archive/24> , Feb. 1).

ACC has similarly pressed EPA on its formaldehyde assessment, which is also more than 20 years old and has been delayed indefinitely, and other controversial chemicals like hexavalent chromium and phthalates.

Those results have raised the ire of public health advocates.

"The greatest impediment to protecting the public from toxic chemicals in everyday products is the money spent by the chemical industry in Washington to block legislative action to reform TSCA, and to prevent government scientists from taking steps to better-inform the public," said

Daniel Rosenberg of the Natural Resources Defense Council.

Jason Rano of the Environmental Working Group said that industry could have put those millions of dollars to better use.

"Clearly, it paid off to be a lobbyist for the chemical industry last year," he said. "Instead of spending its millions to block tougher public health protections of dangerous chemicals, the ACC could have used those resources to help build a safer generation of products we're all exposed to every day."

Wading into politics

ACC's lobbying total was also boosted because the group aired television and radio ads for the first time in recent history.

The group aired television spots <http://www.youtube.com/watch?v=rJLTc7gRcKI&feature=plcp&context=C3d9cbb4UDOEgsToPDskKKsQw4rq0NdfiJfHDkSZw5> that tout support for domestic energy production and small businesses in the districts of Republican Reps. John Shimkus of Illinois, Tim Murphy of Pennsylvania and Ed Whitfield of Kentucky, as well as Democratic Reps. Cedric Richmond of Louisiana and Gene Green of Texas. Whitfield and Shimkus are chairmen of House Energy and Commerce subpanels on issues relating to chemical manufacturing, and Green is a ranking member on one.

ACC aired similar ads for Republican Sens. Scott Brown in Massachusetts and John Barrasso in Wyoming.

Kolton said ACC intends to do more television ads this year but that it remains to be seen whether the group wades fully into election-year politics and backing specific candidates. "We are evaluating as we go," she said.

ACC's political action committee has been active so far this cycle as well. PAC dollars come from a different pot than lobbying funds and typically consist largely of employee contributions.

The PAC contributed nearly $78,500 to federal candidates through the end of 2011, according to the Center for Responsive Politics. That is significantly less than the $294,000 it gave to federal candidates last cycle,

the most ACC's PAC has ever dished out. It is likely, though, that ACC's campaign contributions will ramp up as the election approaches this year.

There has been a significant partisan shift in the contributions, however. The Center for Responsive Politics breakdown shows the ACC PAC has given nearly 70 percent of its contributions to Republicans. In the 2010 cycle, a narrow majority of its contributions -- 54 percent -- went to Democrats.

The shift may be partially explained by Republicans -- who are generally more sympathetic to ACC's agenda -- taking control of the House in 2010, giving them more control over the congressional agenda.

Some of the PAC's most notable contributions this cycle have been $6,000 to Whitfield as well as $5,000 to Shimkus, Barrasso and House Majority Leader Eric Cantor (R-Va.). On the Democratic side, the PAC has given $5,000 to Sens. Joe Manchin of West Virginia and Ben Nelson of Nebraska as well as $2,500 to House Minority Whip Steny Hoyer of Maryland.

With a politically charged climate in Congress, can meaningful policy on shale gas exploration, energy efficiency and energy regulations move in the near term? During today's OnPoint, Cal Dooley, president and CEO of the American Chemistry Council, exclusively discusses his organization's new advocacy and awareness campaign with E&ETV. The campaign, Chemistry to Energy, focuses on the chemistry industry's role in the United States' economic recovery. Dooley weighs in on the controversy surrounding shale gas exploration and the exportation of liquefied natural gas to Asian and European markets. Today's OnPoint will air at 10 a.m. EST.

FW: NEWS UPDATES: Industry Urges EPA To Apply IRIS Fixes To Pending BaP Cancer Assessment (Risk Policy Report)

Martyn Smith to: Bob Sonawane 06/12/2012 03:51 PM
Cc: Kate Guyton
Please respond to martynts

I would be very interested in learning more about the "upcoming weight-of-evidence framework." Cited in the article below. There are many problems with the NAS one.

Best, Martyn

Martyn T. Smith, Ph.D.
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From: Bob Sonawane [mailto:Sonawane.Bob@epamail.epa.gov]
Sent: Tuesday, June 12, 2012 6:47 AM
To: Martyn Smith
Subject: NEWS UPDATES: Industry Urges EPA To Apply IRIS Fixes To Pending BaP Cancer Assessment (Risk Policy Report)

Industry Urges EPA To Apply IRIS Fixes To Pending BaP Cancer Assessment

Posted: June 11, 2012

An ad hoc coalition of industry groups is urging EPA to incorporate various improvements to the agency's Integrated Risk Information System (IRIS) program into an updated cancer risk assessment for benzo(a)pyrene (BaP), findings that EPA will eventually use as a benchmark to determine relative carcinogenicities of other polycyclic aromatic

hydrocarbons (PAHs).

In a June 4 letter to IRIS Director Vincent Cogliano, the coalition suggests it has been left in the dark on the approach EPA will use to update its 1994 cancer risk assessment for BaP, one of the most commonly known PAHs -- the ubiquitous class of chemicals that can be produced from incomplete combustion and are found in crude oil, asphalt, vehicle emissions and other sources.

EPA's approach to the BaP assessment is of particular concern to industry because the agency intends to use its assessment of BaP to estimate other PAHs' carcinogenicity by using BaP as an index or reference chemical for calculating other PAHs' potencies relative to BaP's. The agency uses a similar approach -- known as relative potency factors (RPFs) -- to assess dioxins.

The industry concerns stem from the time it is taking the agency to complete the assessment -- work started in 2004 -- and a series of changes EPA has taken during those eight years to improve the process for creating IRIS assessments. Many of these changes seek to address criticism from the National Academy of Sciences (NAS), the Government Accountability Office (GAO), industry and peer-review panels on both procedural and scientific grounds.

EPA implemented some of the changes, such as publishing literature reviews for comment and holding listening sessions during the comment period on a draft IRIS assessment, several years ago following a 2009 GAO report. It criticized the lengthy process for creating the IRIS documents as putting the IRIS program at "high risk" of obsolescence.

Industry has aggressively touted the National Academy of Sciences' (NAS) 2011 review of the draft formaldehyde assessment in raising pressure on EPA to overhaul its IRIS program, particularly its recommendations regarding weight of evidence analysis. Since the NAS criticisms, EPA has adopted additional steps to reform the program -- including creating a standing SAB panel to review its draft assessments and a peer consultation step early in the development of major IRIS assessments. Agency staff is crafting other efforts to respond to the recommendations, such as an upcoming weight-of-evidence framework.

"In recent years, the IRIS program has implemented several improvements to enhance accessibility and transparency by increasing stakeholder participation," the industry coalition writes. "Several of the steps introduced in 2008, 2009 and 2011 do not appear to have been implemented for the BaP assessment."*Relevant documents are available at InsideEPA.com.* (*Doc ID:* *2401404*)

The industry coalition questions whether a literature search for BaP has occurred and whether a listening session has been held. The group also asks whether the BaP assessment has been labeled a "major assessment," and subject to a higher level of peer review by the agency's Science Advisory Board (SAB) rather than a contractor-run panel of experts.

An agency source tells *Inside EPA* that the BaP cancer update is a "major assessment" and as such will undergo external peer review by an SAB panel. But the source adds that the external peer consultation "to my knowledge has not been scheduled."

EPA says in its April report to Congress that it is currently in the second of three phases of implementing the recommendations. But one industry source says the BaP assessment's age calls into question whether the agency's updated assessment will sufficiently incorporate the recent changes EPA has made.

"If EPA's been developing this for years, are they going to grandfather it in under the old process? We don't know," the source says.

EPA IRIS staff have admitted at conferences that IRIS assessments started before the NAS formaldehyde report will reflect the recommendations in varying degrees. At a

minimum, the reports have been condensed per NAS suggestions, include a new preamble explaining the agency's approach to the assessment and new graphics intended to clarify EPA conclusions. IRIS management has also noted in public remarks that the Academy did not recommend that EPA halt the program while implementing the recommended changes.

The industry source says EPA's approach to the BaP assessment is especially crucial because the resulting assessment would carry major implications for EPA's upcoming effort to use BaP as a reference chemical for calculating RPFs for other PAHs.

The coalition letter notes how the BaP assessment "is prominently linked" to the agency's RPF calculation effort, and asks, "Will the timing of procedural steps for the BaP assessment impact finalization of the RPF document?"

EPA in draft guidance proposed using RPFs to assess the carcinogenicity of a range of other PAHs. But the same industry coalition criticized that document -- *Development of a Relative Potency Factor Approach for PAH Mixtures* -- after it was released for external peer review in February 2010.

The same industry coalition came together then in arguing that the RPF approach is flawed because relying on the toxicity of a single chemical does not accurately predict the toxicity of multiple PAHs in mixtures. They called on EPA to delay finalizing the RPF document until after the agency had updated its 1994 cancer assessment of the risks posed by BaP (*Risk Policy Report* , June 29, 2010).

An SAB panel in June 2010 strongly criticized EPA's planned approach for assessing the cancer risks of PAHs, charging that the agency's approach was inadequate for assessing such a wide range of chemicals. The panel agreed that BaP was the most logical choice to serve as an index or reference chemical because EPA has the most data on it.

But the panelists validated industry concerns that cancer risk data for BaP was more than 15 years old, stipulating that EPA needed to finish updating the 1994 IRIS assessment of BaP's cancer potency before finalizing its RPF approach. The 1994 IRIS assessment characterizes BaP as a probable human carcinogen, and set a cancer slope factor of 7.3 per milligram per kilogram body weight per day.

The re-assessment is scheduled to be completed by the end of fiscal year 2012, according to EPA's IRIS Track website. -- *Puneet Kollipara*

E

RE: Fw: NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)

Kate Guyton to: Rusyn, Ivan I 06/12/2012 02:40 PM

Are you suggesting looking before leaping...? ;-)

"Rusyn, Ivan I" Did she look at pubmed for "how much molecula... 06/12/2012 01:43:13 PM

From: "Rusyn, Ivan I" <iir@unc.edu>
To: Kate Guyton/DC/USEPA/US@EPA
Date: 06/12/2012 01:43 PM
Subject: RE: Fw: NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)

Did she look at pubmed for "how much molecular data is out there"?..

Sent from my Samsung smartphone on AT&T

-------- Original message --------
Subject: Fw: NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)
From: Kate Guyton <Guyton.Kate@epamail.epa.gov>
To: "Rusyn, Ivan I" <iir@unc.edu>
CC:

-----Forwarded by Kate Guyton/DC/USEPA/US on 06/12/2012 01:26PM -----

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EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion
Posted: June 11, 2012

EPA scientists are examining molecular data for several chemicals undergoing risk assessments in efforts to further understand how these newer types of information can inform agency analyses as part of the agency's ongoing effort to transition to the "next generation" (NexGen) of risk assessment, including both these data and traditional toxicology.

Agency scientists hope to use the data to further inform the ongoing Integrated Risk Information System (IRIS) assessments for five high-interest chemicals -- benzo(a)pyrene (BaP), chloroform, arsenic, hexavalent chromium (Cr6) and formaldehyde -- said Ila Cote, senior science adviser to the Immediate Office of the Director the National Center for Environmental Assessment. Depending on the amount and quality of the data available, Cote said, risk assessors may be able to incorporate the information into the IRIS assessments to varying degrees.

But Cote warned that she didn't want to "overpromise" on what the effort could deliver because it is still unclear how much molecular data there are for each of the five chemicals and their quality. Cote spoke at a May 30 meeting of a Science Advisory Board (SAB) committee charged with advising EPA on how to incorporate new computational toxicology methods into risk assessment. Relevant documents are available on InsideEPA.com. (Doc ID: 2401405)

EPA's NexGen program seeks to determine how to incorporate newer computational and systems biology approaches into risk assessment. It also seeks to create a tiered approach that requires greater burdens of evidence on assessments for higher-priority chemicals. As part of the effort the agency is seeking to identify chemicals with a wealth of data available and "reverse engineer" prototypes from them, and create decision rules for using the newer types of data into risk assessments.

With thousands of chemicals in commerce for which EPA does not have toxicity testing results, the agency is grappling with how to speed up chemical risk assessments to get more chemicals tested. At the same time, EPA must ensure that the new molecular, cellular and computational methods can accurately supplement, or in some cases replace, existing animal-based in vivo methods that are seen by many as costly and time-consuming.

Cote's presentation identifies the five chemicals as part of the highest of the NexGen framework's three tiers, which is reserved for those chemicals that come with "nationwide exposure and nationwide risk," Cote said at the meeting. Tier III chemicals, according to the presentations, can draw on all "policy-relevant" data ranging from high-throughput to low-throughput and from molecular to macroscopic-level, but the resulting risk assessments also come with the highest burden of evidence given the priority assigned to the chemical, according to the presentation.

EPA has been working on "proof of concept" prototypes on three chemicals -- polycyclic aromatic hydrocarbons (PAHs), benzene and ozone. The agency hopes to "extend what is learned to [Tier III] chemicals with less data," according to the presentation. Another benefit EPA hadn't initially predicted, Cote said, is that the agency can use what is learned to help resolve issues with chemicals for which questions remains despite a wealth of traditional data existing.

Cote did not explain how extensively the data might influence the final risk assessments, as the agency is still evaluating the data. But she emphasized that "in all of these there will be a peer-review process of what we've done and opportunity to engage in scientific community and refine these processes as we move forward."

Cote said EPA would seek to finish assessing the BaP microscopic data in June 2012 which would come before the agency's projected fourth-quarter fiscal year 2012 release of a draft reassessment for public comment and peer review. The assessment would serve to update a 1994 analysis of BaP, one of the most well-known PAHs, the ubiquitous class of chemicals that are formed from incomplete combustion of wood, fossil fuels and food and are found in crude oil, asphalt, vehicle emissions and other sources (see related story).

The BaP assessment would be of special importance because a SAB panel asked the agency in 2010 to finish the BaP update assessment before finalizing guidance on determining carcinogenicities of other PAHs by using BaP as an index chemical through a relative potency factor approach. An agency source tells Inside EPAthat studying the BaP molecular data probably will not delay the BaP cancer assessment update.

It was not immediately clear how the microscopic-level data would influence the final IRIS assessment of formaldehyde, a chemical for which the draft assessment came under fire from industry and a peer-review panel at the National Academy of Sciences. The EPA presentation says the agency expects to finish the NexGen information for the formaldehyde assessment by February 2013, with the assessment's release for peer review occurring as early as the third quarter of fiscal year 2013.

Industry, meanwhile, has sought to convince EPA that the carcinogenicity of Cr6 -- the particular form of chromium EPA is assessing -- does not occur mutagenically but instead through different a mode of action (MoA) that would not require EPA to use a linear low-dose extrapolation that generally produces stricter risk values. The EPA presentation says the agency will finish studying and assembling the Cr6 molecular data by 2013. EPA's website

lists the oral and inhalation IRIS assessment, which it delayed to consider the industry's claims on the MoA, as due out for peer review and public comment also in 2013.

The agency plans to finish studying and potentially assemble the data on chloroform by December 2012 and on arsenic by 2014, according to the presentation. -- Puneet Kollipara

Elizabeth Erwin
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Fw: NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)

Elizabeth Corona to: Kate Guyton 06/12/2012 09:56 AM

Shit...
Elizabeth Erwin

----- Original Message -----
From: Elizabeth Erwin
Sent: 06/12/2012 09:35 AM EDT
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Subject: NEWS UPDATES: EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion (Risk Policy Report)

EPA Studying Molecular Data On Five Chemicals For Possible IRIS Inclusion

Posted: June 11, 2012

EPA scientists are examining molecular data for several chemicals undergoing risk assessments in efforts to further understand how these newer types of information can inform agency analyses as part of the agency's ongoing effort to transition to the "next generation" (NexGen) of risk assessment, including both these data and traditional toxicology.

Agency scientists hope to use the data to further inform the ongoing Integrated Risk Information System (IRIS) assessments for five high-interest chemicals -- benzo(a)pyrene (BaP), chloroform, arsenic, hexavalent chromium (Cr6) and formaldehyde -- said Ila Cote, senior science adviser to the Immediate Office of the Director the National Center for Environmental Assessment. Depending on the amount and quality of the data available, Cote said, risk assessors may be able to incorporate the information into the IRIS assessments to varying degrees.

But Cote warned that she didn't want to "overpromise" on what the effort could deliver because it is still unclear how much molecular data there are for each of the five chemicals and their quality. Cote spoke at a May 30 meeting of a Science Advisory Board (SAB) committee charged with advising EPA on how to incorporate new computational toxicology methods into risk assessment. *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2401405)

EPA's NexGen program seeks to determine how to incorporate newer computational and systems biology

approaches into risk assessment. It also seeks to create a tiered approach that requires greater burdens of evidence on assessments for higher-priority chemicals. As part of the effort the agency is seeking to identify chemicals with a wealth of data available and "reverse engineer" prototypes from them, and create decision rules for using the newer types of data into risk assessments.

With thousands of chemicals in commerce for which EPA does not have toxicity testing results, the agency is grappling with how to speed up chemical risk assessments to get more chemicals tested. At the same time, EPA must ensure that the new molecular, cellular and computational methods can accurately supplement, or in some cases replace, existing animal-based *in vivo* methods that are seen by many as costly and time-consuming.

Cote's presentation identifies the five chemicals as part of the highest of the NexGen framework's three tiers, which is reserved for those chemicals that come with "nationwide exposure and nationwide risk," Cote said at the meeting. Tier III chemicals, according to the presentations, can draw on all "policy-relevant" data ranging from high-throughput to low-throughput and from molecular to macroscopic-level, but the resulting risk assessments also come with the highest burden of evidence given the priority assigned to the chemical, according to the presentation.

EPA has been working on "proof of concept" prototypes on three chemicals -- polycyclic aromatic hydrocarbons (PAHs), benzene and ozone. The agency hopes to "extend what is learned to [Tier III] chemicals with less data," according to the presentation. Another benefit EPA hadn't initially predicted, Cote said, is that the agency can use what is learned to help resolve issues with chemicals for which questions remains despite a wealth of traditional data existing.

Cote did not explain how extensively the data might influence the final risk assessments, as the agency is still evaluating the data. But she emphasized that "in all of these there will be a peer-review process of what we've done and opportunity to engage in scientific community and refine these processes as we move forward."

Cote said EPA would seek to finish assessing the BaP microscopic data in June 2012 which would come before the agency's projected fourth-quarter fiscal year 2012 release of a draft reassessment for public comment and peer review. The assessment would serve to update a 1994 analysis of BaP, one of the most well-known PAHs, the ubiquitous class of chemicals that are formed from incomplete combustion of wood, fossil fuels and food and are found in crude oil, asphalt, vehicle emissions and other sources (*see related story*).

The BaP assessment would be of special importance because a SAB panel asked the agency in 2010 to finish the BaP update assessment before finalizing guidance on determining carcinogenicities of other PAHs by using BaP as an index chemical through a relative potency factor approach. An agency source tells *Inside EPA* that studying the BaP molecular data probably will not delay the BaP cancer assessment update.

It was not immediately clear how the microscopic-level data would influence the final IRIS assessment of formaldehyde, a chemical for which the draft assessment came under fire from industry and a peer-review panel at the National Academy of Sciences. The EPA presentation says the agency expects to finish the NexGen information for the formaldehyde assessment by February 2013, with the assessment's release for peer review occurring as early as the third quarter of fiscal year 2013.

Industry, meanwhile, has sought to convince EPA that the carcinogenicity of Cr6 -- the particular form of chromium EPA is assessing -- does not occur mutagenically but instead through different a mode of action (MoA) that would not require EPA to use a linear low-dose extrapolation that generally produces stricter risk values. The EPA presentation says the agency will finish studying and assembling the Cr6 molecular data by 2013. EPA's website lists the oral and inhalation IRIS assessment, which it delayed to consider the industry's claims on the MoA, as due out for peer review and public comment also in 2013.

The agency plans to finish studying and potentially assemble the data on chloroform by December 2012 and on arsenic by 2014, according to the presentation. -- *Puneet Kollipara*

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NEWS UPDATES: Draft EPA Analysis Sees Stricter Limit For Ethylene Oxide , Worrying Industry (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew

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Draft EPA Analysis Sees Stricter Limit For Ethylene Oxide, Worrying Industry

Posted: June 11, 2012

EPA is proposing to strengthen its publicly released 2006 draft toxicity value for ethylene oxide (EtO), a chemical intermediate and medical sterilizer, according to a 2011 working draft Integrated Risk Information System (IRIS) assessment, worrying industry officials who fear the upcoming final version will adopt a limit at least as strict as proposed in 2006.

According to the 2011 working draft IRIS assessment crafted by EPA's National Center for Environmental Assessment (NCEA), the agency is proposing a slightly steeper estimate of cancer potency -- or inhalation unit risk (IUR) -- of 1.8 x 10^-3 per micrograms per cubic meter (ug/m^3), representing a higher lifetime risk from the 1.5 x 10^-3 per ug/m^3 value the agency proposed publicly in 2006. *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2401408)

The 2011 draft assessment also maintains agency findings from 2006 that the chemical is a mutagen -- a finding that EPA's cancer assessment policy generally requires risk assessors to use conservative, linear default assumptions that assume no safe level of exposure -- and also retains the use of additional safety factors to protect children from exposures, one of the first times EPA has done so.

Use of the additional safety factor resulted in EPA strengthening its estimates for lifetime risk of contracting cancer from EtO exposure by roughly two-thirds, as the agency multiplies the cancer risk from ages 0 to 2 by a factor of 10 and the risk from ages 2 to 16 by a factor of three.

The draft assessment also indicates that EPA appears to address unanimous calls by its Science Advisory Board (SAB) to revise the exposure data it used in the 2006 draft IRIS assessment -- a hurdle that had forced the agency to revise the assessment (*Risk Policy Report* , Jan. 24, 2008).

In particular, the SAB calls for EPA to conduct "direct analysis of the individual exposure and cancer outcome data" collected by the National Institute for Occupational Safety & Health (NIOSH), rather than the "grouped data" presented in a 1993 epidemiological study that organized the NIOSH information according to exposure level and was utilized by EPA in crafting its draft EtO cancer risk models. In the 2011 draft, EPA says it consulted with one of the investigators from the NIOSH cohort studies to come up with an alternative model that tries to address the SAB's concern.

The final assessment is slated for publication at the end of fiscal year 2012, according to EPA's website, though the agency has already delayed issuance of the document several times.

But the draft findings are raising concerns from chemical industry officials. Bill Gulledge, senior director with the American Chemistry Council, said during a workshop at the Texas Council on Environmental Quality on May 24that his group found the IRIS document in a search on EPA's website a few months ago.

He said that the study's findings suggest that the risk estimates in the agency's final IRIS assessment could be largely similar to the draft, carrying potentially significant regulatory implications for companies using the chemical.

"The bottom line is, in this document, we haven't seen any [significant] change" from EPA's 2006 draft, Gulledge said. "I say the big 'but' is that the final IRIS assessment is not available. It may indicate that this may all change. We just don't know."

EtO is registered as a pesticide under the Federal Insecticide, Fungicide & Rodenticide Act, and it is used in health care facilities to sterilize medical equipment. The chemical is also used as an intermediate in the production of other chemicals such as ethylene glycol, which in turn is used to produce antifreeze, or to produce surfactants in

household and industrial detergents.

But EPA and others have long been concerned that exposure to the chemical poses risks of breast and lymph cancers. Since February 2010, EPA has required a single-chamber process -- where medical equipment sterilization and aeration occur in the same chamber -- for ethylene oxide sterilization in hospitals and health care facilities such as clinics and nursing homes, as a means of reducing potential long-term non-cancer and cancer risks for workers in those facilities.

The 2006 draft IRIS assessment for EtO found sufficient evidence for a mutagenic mode of action, and, consistent with the agency's 2005 cancer assessment policy, proposed boosting its 1985 IUR of 1 x 10^-4 per ug/m^3 to a stricter-risk value of 1.5 per ug/m^3.

The new assessment relied on EPA's 2005 cancer assessment policy, which generally requires risk assessors to use conservative linear risk models that assume no safe level of exposure when substances cause cancer by genetic mutation or if their mode of action is unknown.

The draft assessment was also one of the first to rely on EPA's supplemental cancer assessment policy that allows the agency to use additional risk safety factors to protect children's health when setting toxicity values -- an approach that agency science advisers later endorsed.

Although multiple bodies -- the National Toxicology Program and the International Agency for Research on Cancer (IARC) -- have classified EtO as a known carcinogen, other bodies such as the American Conference of Government Industrial Hygienists (ACGIH) and NIOSH have cited limited evidence of EtO's carcinogenicity in humans in classifying it as a suspected carcinogen.

EPA acknowledges these differences, saying in the draft that "although evidence of carcinogenicity from human studies was deemed short of conclusive on its own, EtO is characterized as carcinogenic to humans by the inhalation route of exposure based on the total weight of evidence," in accordance with EPA's 2005 cancer assessment guidelines.

EPA said that supporting information includes strong, but less than conclusive, evidence of lymphohematopoietic cancers and some evidence of breast cancer in EtO-exposed workers, extensive evidence of carcinogenicity in laboratory animals, clear evidence that EtO is genotoxic and sufficient weight of evidence to support a mutagenic mode of action for EtO carcinogenicity, and strong evidence that the key precursor events are anticipated to occur in humans and progress to tumors, including evidence of chromosome damage in humans exposed to EtO.

ACC's Gulledge pointed to the institutional disagreement and the range of existing evidence saying ACC would probably consider EtO to be a suspected carcinogen and that its carcinogenicity, if any, is likely to be weak. Additionally, Gulledge in his presentation took issue with the risk values for carcinogenicity that EPA gave both in its 2006 IRIS draft and in the 2011 draft, saying they reflect additional exposure to EtO that is roughly three orders of magnitude lower than what is endogenously occurring in the human body.

Gulledge cited both of those points in comparing the EPA draft assessment for EtO with the agency's much-criticized draft IRIS assessment of formaldehyde, which came under fire in a scathing National Academy of Sciences (NAS) report last year.

The agency concluded in its formaldehyde assessment that the chemical is carcinogenic, could cause lymphohematopoietic cancers -- a class of cancers that includes leukemia -- as well as nasal cancers and other non-cancer effects. EPA also calculated a strict, and highly controversial, IUR. NAS is preparing to undertake a broader review of the agency's IRIS program.

"I looked at this evidence, and said this is an awful lot like formaldehyde, where you have a low potential mutagen, you have exposure levels that are naturally occurring that are way above the level EPA is proposing as its unit risk estimate," Gulledge said in a phone interview.

He implored EPA to have a more rigorous, detailed characterization of the mode of action by which the agency alleges EtO to cause cancer, to better consider human exposures in the context of background EtO levels in setting reference doses and "using lessons from the NAS review of formaldehyde," such as being more transparent with how it conducts its weight-of-evidence analysis.

Still, Gulledge signaled that ACC would very likely continue its criticism of the final IRIS assessment if it's highly similar to the 2006 draft, and would consider even putting out a peer-reviewed article in response. "We'll come up with

what we feel the risk should be, at least our thoughts on it, and back it up with all the science that we can," Gulledge said in the interview.

Gulledge also criticized EPA's use of additional safety factors to protect children. He said that the use of such age dependent adjustment factors is generally appropriate but should be used "on a chemical-specific basis" when an exposure pathway for children can be established, and "there really isn't an exposure pathway [for EtO] that's going to lead to children's exposure." -- *Puneet Kollipara*

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NEWS UPDATES: Advisers Split On Vanadium Pentoxide 'Likely' Carcinogenicity Finding (Inside EPA)
Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew
03/13/2012 09:02 AM

Advisers Split On Vanadium Pentoxide 'Likely' Carcinogenicity Finding

Posted: March 12, 2012

A group of expert reviewers are split over EPA's proposed cancer classification for vanadium pentoxide (V2O5), while raising questions about the agency's conclusions for both its cancer and non-cancer assessments of the metal.

The reviewers raised concerns about both the cancer and non-cancer portions of the IRIS assessment during their meeting March 7 in Arlington, VA, and were unable to reach consensus over EPA's proposed listing of V2O5 as a likely human carcinogen. Reviewers were unable to agree on whether there was sufficient V2O5 toxicology data available to conclude it is a likely carcinogen, rather than showing suggestive evidence of carcinogenicity.

For both cancer and non-cancer evaluations of the metal, the reviewers suggested EPA does not sufficiently acknowledge the limited available data in its risk assessment. One of the panelists also expressed concern over an issue industry has previously raised with the assessment -- whether the test material in one of the non-cancer studies was V2O5 or another form of vanadium.

"What were the selection criteria and how do you decide what studies get cited more than others," asked one reviewer, Yiliang Zhu, a professor at the University of South Florida. In the absence of selection criteria, "I have no idea why one study gets selected and why another has not."

As it is, Zhu added, the agency seems to have poor quality studies and a high uncertainty factor to compensate, but "the key approach to addressing the uncertainty is not really saying 'It's not a good study but I'm going to use it anyway.'"

Similarly, with regard to EPA's non-cancer evaluation, the panelists said that EPA should bolster its findings by assessing multiple endpoints and explain why it used the studies and endpoints it did.

V2O5 is made from the spent catalysts from oil refineries and power plants and is used as a strengthener in steel and titanium alloys, making the metal lighter and stronger, qualities that have made the substance attractive to the military for uses in weapons, vehicles and other equipment. The material is also finding uses as pigment in some yellow paints and in rechargeable batteries.

In its new risk assessment for V_2O_5, which was released in September, EPA sets a reference concentration (RfC), or safe limit for inhalation, of 1×10^{-5} mg/m^3; an oral reference dose (RfD), or safe limit for ingestion, of 9×10^{-4} mg/kg-day; and further concludes that the substance is "likely to be carcinogenic to humans."

EPA's air office requested the IRIS assessment because the metal is used as a catalyst to reduce nitrogen oxides emissions from power plants and in diesel engines. Further, EPA is weighing how to regulate spent refinery catalyst under its pending amendments to the definition of solid waste.

The Vanadium Producers and Recyclers Association (VPRA) in presentations during the listening session in Arlington, VA, and other groups are calling on EPA to exclude the catalyst from the broad rule to ensure it is not regulated under strict hazardous waste provisions and can still be processed by third-party recyclers.

However, industry is arguing that EPA's draft conclusions are overly conservative, pointing out that the limits are orders of magnitude below naturally occurring background level, and are skewed by flawed data the agency used in crafting the assessment (*Risk Policy Report* , Dec. 13).

The crux of the problem, industry says, is that the assessment relies on two studies that have considerable flaws -- a National Toxicology Program (NTP) effort from 2002 in which the test material changed color, raising questions about its chemical make up, and Mountain et. al, 1953, which opponents argue is outdated and predates good laboratory practices.

However, Vince Cogliano, head of the IRIS program, urged the panel to keep in mind that assessments are based on the existing data despite their limitations. "We have to deal with the data set we have, not the data set we wish we had," Cogliano said. "This is the database we have and this is what the review should focus on."

While the panel acknowledged that limitation, some members argued that the shortcomings of the body of research are so great that they put into question the validity or feasibility of the assessment.

For example, panel member Ralph Kodell, a professor at the University of Arkansas for Medical Sciences, noted that in using the Mountain study for determining the RfD, "it may be all there is but I don't think that makes it adequate for setting an RfD." Given the age of the study and its lack of standard timeframes and practices, "I don't know that you can believe the numbers, I don't see how you can. If this is all there is, it's not good enough," Kodell said. "I don't know what the RfD would mean when you're finished."

However, given that the Mountain study is the only existing animal study on ingestion of V_2O_5, Zhu argued that "if you want to use this study, that's fine, but then you need to discuss the limitations."

Reviewers had fewer concerns with the agency's determined RfC, although raised questions

about the chemical make up of the test material, which changed colors during the course of the NTP study, and the end point EPA choose as the basis for its calculation.

"This study is probably arguably the best designed study despite the limitations," Zhu said. "My concern here is really why at the end we decide to use a single sex and a single end point." If the NTP study is to be used as the principle study, then the agency should take into account the broad array of endpoints it considers, he said. In particular, the RfC is based on red blood cell counts in female rats, but "you really should consider both species and both sexes" and other health effects, Zhu said.

Agency officials at the meeting said they were open to using multiple studies and endpoints to determine safe levels of a compound, but need guidance on how to accomplish that. "The National Academy of Sciences said we should think more expansively about using more studies for driving the reference values," Cogliano said, adding that the panel should make recommendations on how to move forward with that.

The NTP study also highlights an underlying issue with the document concerning an inconsistency by the agency to ensure that it was sticking to just V2O5 in the documentation behind its assessment and in the final document itself. V2O5 is bright orange in color, but easily combines with other compounds and changes valence states. Very rarely is it in V2O5 form, said Craig McLauchlan, a panel member and chemist at Illinois State University.

The NTP test material, which started as orange and then changed hues to, among other things, a shade of purple, likely changed into a different form of vanadium, putting the results into question. Further, McLauchlan raised questions about EPA's use of the term "vanadium" in the beginning of the assessment and cautioned the agency to be clear that it was just talking about V2O5 and not the many other vanadium compounds and degredates. "The question becomes are we talking about V2O5 or are we talking about vanadium, we need to be clear," McLauchlan said, adding that the vague language from EPA "really does undermine the whole document."

The panel, meanwhile, was split over the agency's determination that V2O5 is a "likely human carcinogen" based on the presence of tumors in female mice, with McLauchlan and several other reviewers arguing that the evidence was not strong enough to reach that conclusion and that the material is better classified as having "suggestive evidence of human carcinogenicity."

"There is no silver light that says if it's a carcinogen or not," Zhu said. "If we accept EPA's [cancer] guideline, this is probably the closest description, but if I had the choice I would say this is between suggestive and likely."

Max Costa, a member of the panel and professor at the New York University School of Medicine, however, said that the data about a potential mode of action, and existing knowledge on the differences between how rats and humans respond to metals, give "reason to suspect it is a likely carcinogen."

"Mechanistically it's plausible that it could be a carcinogen," Costa said. "The data for the mice are very strong, the data for the rat are not much . . . but you see that a lot" with studies on

metals.

Many of the issues with the assessment raised by peer reviewers and industry mimic calls that the National Academy of Sciences laid out last year in chapter 7 of its review of EPA's formaldehyde assessment. That document, among other things, called on EPA to better explain why it chooses particular studies as the basis for its reference limits.

EPA has embraced many of the recommendations, which will be reflected in later IRIS assessments, Cogliano said. The V2O5 draft document began its review process just a month after chapter 7 was released, and so in following the NAS call not to stall any pending assessments, "we did not, however, send the doc back through the process, " Cogliano said. "This document is part compliant with the NAS recommendations. Everything that is released going forward will be much more compliant." -- *Jenny Hopkinson*

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